Part 2 - Presentations for the EPA 23rd Annual National Conference on Managing Environmental Quality Systems

April 13-16, 2004 Tampa, Florida

Information Technology / Policy Impacts and How to Proactively Manage the Quality of Information Products

The Top Ten Data Issues Facing the Typical Organization (Thomas Redman, Navesink Consulting Group)

Future Shock – Current and Future Impacts of Information Technology and Information Policy on Management Systems for the Quality of Public and Private Information Products (Jeff Worthington, U.S. EPA)

Retooling the Management System for Quality: How Managers and Quality Mangers May Sharpen Tools and Skills to Effectively Manage Product Quality for Information (Jeff Worthington, U.S. EPA)

Environmental Measurements

Volatile Water Samples at 4 Degrees Celsius: Environmental Folklore or Fact? (Rameen Moezzi, Tetra Tech EM, Inc.)

Ensuring the Quality of Privatized Proficiency Testing Studies (Curtis Wood, Environmental Resource Associates)

Development of Field Analytical Methods for Long-Term Monitoring of Military Important Chemicals (David Splichal, U.S. Army)

Presentations for the EPA 23rd Annual National Conference on Managing Environmental Quality Systems

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Managing Information as a Product

Tools of Quality – An Interactive Session on Identifying Features and Innovative Measurement (Jeff Worthington, U.S. EPA)

10 Laws of Managing Information as a Product (Jeff Worthington, U.S. EPA)

Workshop: ANSI/ASQ E4-2004 Overview (Gary L. Johnson, U.S. EPA)

Presentations for the EPA 23rd Annual National Conference on Managing Environmental Quality Systems

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Intergovernmental Efforts to Unify Environmental Data Quality Policy

Guidance and Tools for Implementing Environmental Quality Systems (Mike Carter, U.S. EPA)

The EDQW: An Integrator of Environmental Quality throughout DoD (Jackie Sample, U.S. EPA)

The Approach of the Uniform Federal Policy on Environmental Quality to Quality Assurance Project Plan (Robert Runyon, U.S. EPA)

Workshop: OEI Update on Quality Improvements

Modeling Value of Information to Set Priorities for Quality Needs (Art Koines, U.S. EPA)

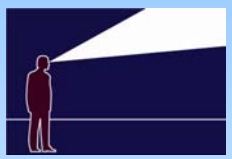
Using the State-EPA Exchange Network to Improve Data Quality and Timeliness (Pat Garvey, U.S. EPA)

Data Standards: Improving Communication Capabilities for Sampling and Analysis Data (Mike Carter and Linda Spencer, U.S. EPA)

Intergovernmental Efforts to Unify Environmental Data Quality Policy (continued form morning)

Quality Assurance/Quality Control for Ordnance and Explosives Investigations and Cleanup (Laura Wrench, Versar, Inc.)

Understanding Analytical Data Quality for Project Managers (Fred McClean, U.S. Navy)



The Top Ten Data Issues Facing the Typical Organization

23rd Annual National Conference on
Managing Environmental Quality Systems
April 2004

Thomas C. Redman, Ph.D.
President, Navesink Consulting Group

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Outline

- Motivation
- How Synthesized and Tested
- The Issues
- What Those With the Best Quality Data Do
- Where We Stand

Motivations

- Need for a "management science" for data.
- Understand the scope of "Data Quality" and put it in context.
- Help organizations start data programs.
- Mend the rifts between Information Technology Departments and "the business."

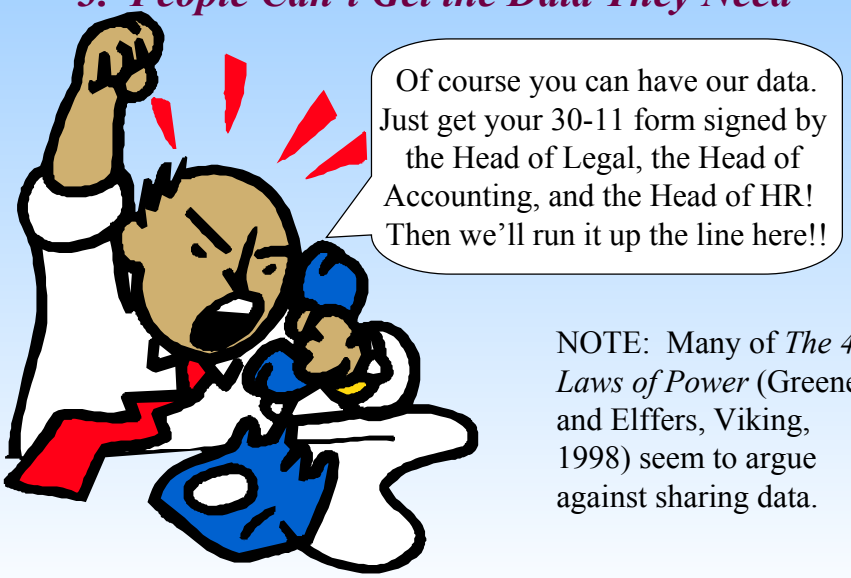
How Synthesized and Tested

- 1993: Question from a CEO: "So what do I have to think about in terms of data?
- 1994: Routine review of research directions.
- 1995: Trial at AT&T
- 1996-present: Tested with dozens of others.
- 1999-present: Increased urgency due to the:
  - Internet
  - Acceleration in growth in data volumes
  - Data Disasters
  - DQ Act, Sarbanes-Oxley

1. Poor Connection Between Data and Business Strategy

2. The Organization Doesn't Know What Data it Has

3. People Can't Get the Data They Need



NOTE: Many of *The 48 Laws of Power* (Greene and Elffers, Viking, 1998) seem to argue against sharing data.

4. There is Simply Too Much Data…

…And Data Volume is Growing by the Minute

"Inside IBM, we talk about 10 times more connected people, 100 times more network speed, 1,000 times more devices, and a million times more data."

(Gerstner, L., quoted in McDougall, P., "More Work Ahead," *Information Week*, December 18-25, 2000, p. 22).

5. Quality is Low

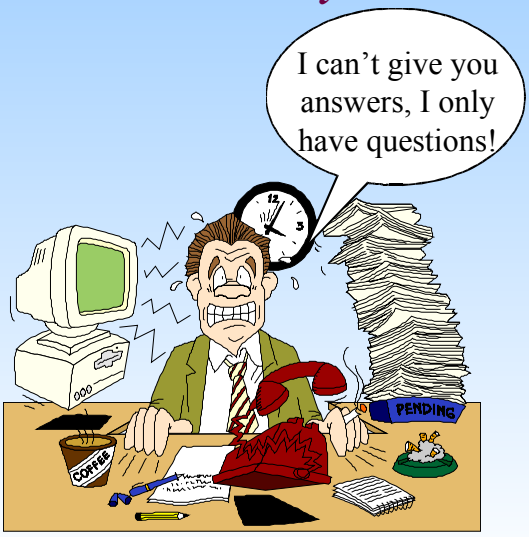
Sometimes bad data makes the national news:

- United States INS advice on visa status to flight schools
- Re-stated Corporate Earnings (e.g., Enron)
- Y2K United States Presidential Election
- Bombing the Chinese Embassy
- Bad medical prescriptions

But most data quality issues are simply buried in the organization

- Typical error rate = 2%
- Easily measured cost to organization = 10% of revenue
- Possible total cost = 20% of revenue

6. Cannot Create/Acquire New Data in a Timely Fashion



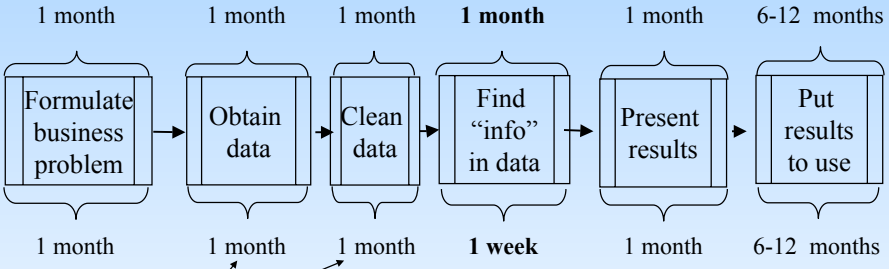
7. The Organization Doesn't Use What It Has Well

Common Definition of Customer: Key to Profits or Diabolical Trap

Mining Customer Data: Undiscovered Gold or Mindless Drivel?

New Tools have not made the Data Mining Process more effective

Old Way with the Old Tools



1 month | 1 month | 1 month | **1 week** | 1 month | 6-12 months

Much longer if data warehouses are needed

New Way with the New Tools

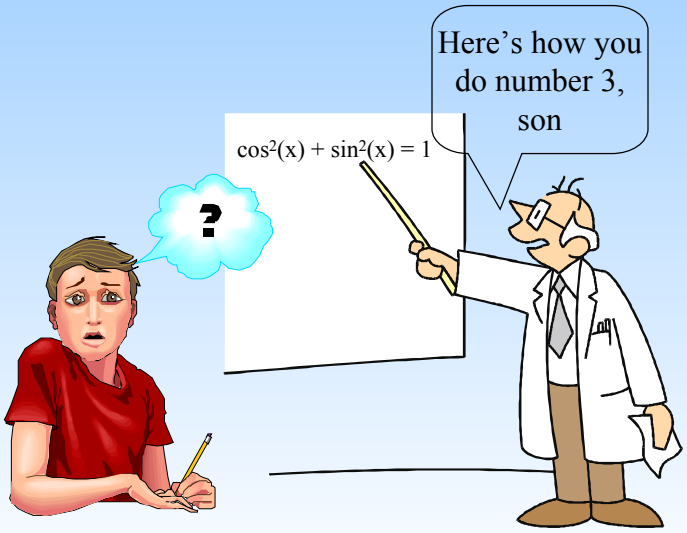
8. Data are at Risk of Being Stolen or Lost

9. People's Rights To Keep Personal Data Private are Not Well-Understood

10. Management Responsibilities are Unclear and the Politics are Brutal

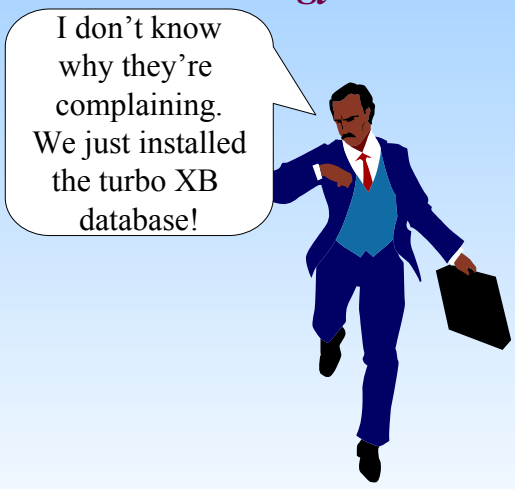
No data issue is so trivial that it doesn't generate enormous political heat!

It is so easy for accountability to shift downstream!!!

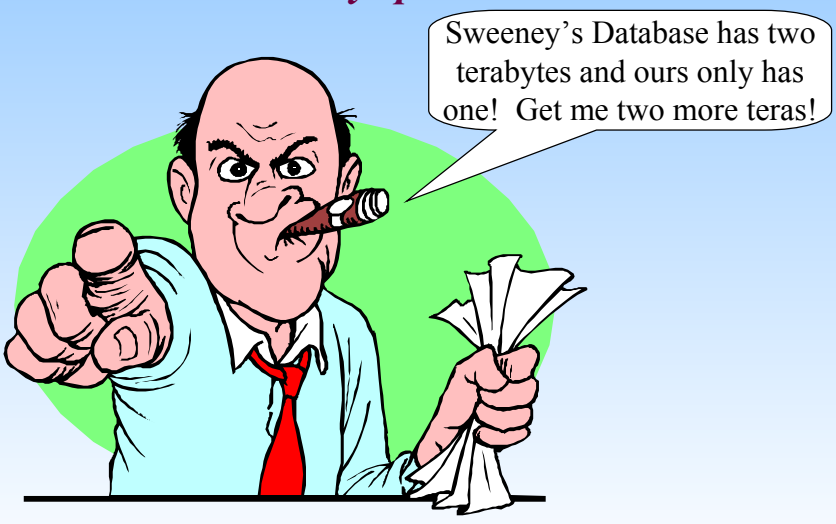


Who is responsible for data quality? Since the data are "in the warehouse," it must be the CIO.

There is considerable appeal of advanced technology



In the Information Age, possession of data conveys power!



Second-Generation Data Quality Systems

Those with the highest quality data assign management accountability for data at their original sources.

These original sources include:

- *External suppliers,* and they use *data supplier management* to obtain the best possible data from these suppliers.
- *Internal information chains,* and they use *information chain management* to create the best possible data.
- In some cases, these responsibilities are codified in *policy.*
- Finally, *leadership* comes from very high levels.

A Database is Like a Lake

Second-Generation Data Quality Systems ™

Those with the highest quality data focus on the most important data:

- Business issues/opportunities
- Customers and customer needs
- Data

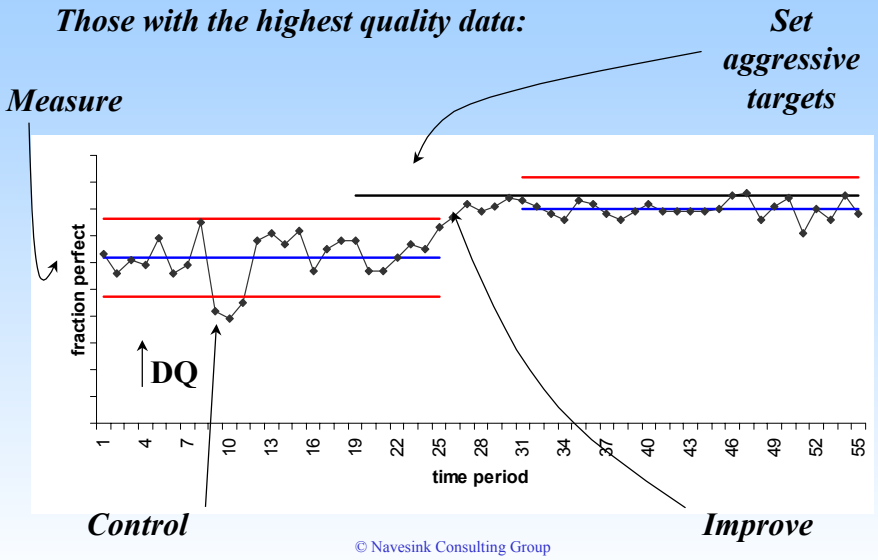
Those with the highest quality data focus on the most "dimensions:"

- Accessibility
- Accuracy
- Clear Definition
- Ease of Interpretation

NOTE: 50% of data are never used by anyone for anything.

Second-Generation Data Quality Systems ™

Those with the highest quality data:

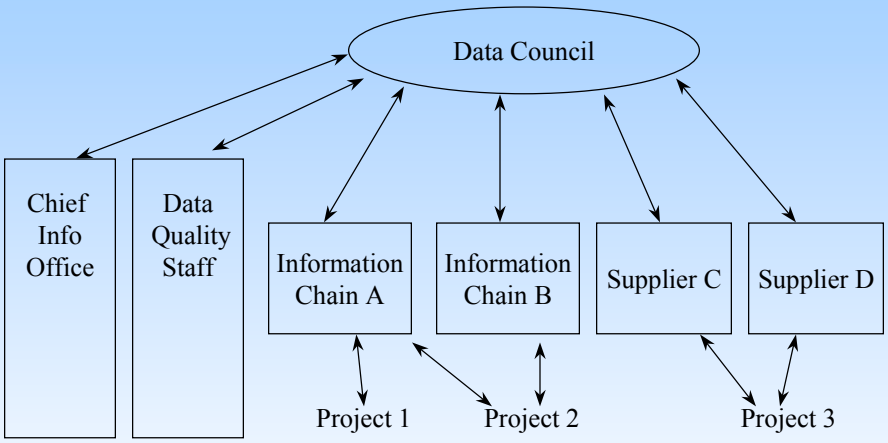


Second-Generation Data Quality Systems ™

Those with the highest quality data manage the data culture. They:

- Distinguish "I" from "IT." They recognize that automating a poorly-defined and –managed process is ill-fated.
- Start small. Early wins.
- Actively manage change.
- Avoid unwinnable battles, especially early on.
- Recognize data as business assets.
- Build data quality in:
  - To the organization
  - To new systems
  - To people's psyche

*Proposed Organization for Data Quality**



*overlaid on current organization

Where Do We Stand (1 of 2)

1. Strategy: Solvable.
2. Knowledge of Data Resource: Solvable (?), with well-managed meta-data processes.
3. Access/Data Sharing: Not solvable. And we may be heading in the wrong direction.
4. Too Much Data: Uncertain. Well-managed meta-data processes help. So do new technologies. But the quantity of data is growing faster than technological advances.
5. Quality. Clearly solvable and a big winner for organizations that do so.

Where Do We Stand (2 of 2)

6. New Data Needs: Uncertain. Well-managed development processes help. But the needs are growing very fast.
7. Usage: Solvable, with well-managed, end-to-end decision processes.
8. Security: Uncertain. While much of the problem stems from lack of attention, hackers are very clever.
9. Privacy: A long way to go.
10. Management: Some good ideas are emerging (process, value of data, etc.), but current management and data flow are mis-aligned.

Questions, Comments, Criticisms

Volatiles Water Samples at 4°C: Environmental Folklore or Fact?

- By Rameen Moezzi/Tetra Tech EM Inc.

Cool to 4°C

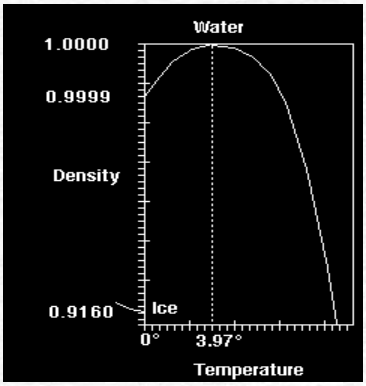
- EPA SW-846

Decline in data quality:

- Degradation - chemical or microbial
- Loss - from container or water

Transport Equipment

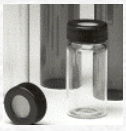
4°C – A Significant Temp



Most bacteria like:

- Neutral pH
- People food
- Moderate temperatures

In-Situ vs Sampled

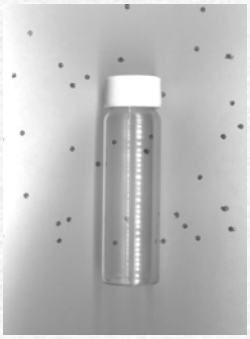
	pH	Temperature
	5-8	15°C
	 **<2**	4°C

Volatilization

- Screw-cap
- Teflon-lined silicone septum
- 40-ml clear glass vial

Closed System?

- Trip blanks
- Molecules are small, VOCs are volatile
- Balloons, bottled water, & caps



CLP

Lab SOW

- Notify if > 10^0C

Data Review Guidelines

- Professional judgment
- No qualifications for samples analyzed within 7 days

Conclusion

- 4°C = Refrigerate
- Cap for volatilization from vial
- SW-846/CLP do not call for resampling
- Need more studies
- CLP SOW – notify if over 10°C

Innovations in Cooler Technology

Ensuring the Quality of Privatized Proficiency Testing Studies

Curtis J. Wood

April 15, 2004

Or

Tax filing round table

History

- Privatized in 1999
- NIST/NVLAP provides accreditation
- NIST accreditation covers a limited suite of water analytes

History

- NIST conducts provider audits
- “NIST is not an oversight body”
- No interim review of quality of PT studies

NELAC

- NELAC program includes many more analytes than EPA/NIST
- NELAC includes more specific PT Provider requirements
- Currently no NELAC PT Provider accreditation program

NELAC

- Relies on NIST accreditation
- NELAC PTOB/PTPA process is still ongoing
- There may be NELAC accredited PT Providers by mid-2005

Summary

- One accreditor +
- Limited scope +
- No oversight =

BUYER BEWARE!

Why worry?

- Most acceptance limits based on assigned value
- Homogeneity
- Stability

What can be done?

- Labs and states must practice due diligence
- Know the requirements
- Check up on their PT Providers

Assigned Value

- NVLAP: mean within 1/3 of laboratory limits ($\leq$ 10%)
- NELAC: mean at ±1.5 s.d. as calculated for the labs under test
- NELAC: standard deviation < 1 s.d. for labs under test

Homogeneity

- "establish at the 95% confidence level that the assigned value is consistent across the production run"
- NELAC Draft 2004 standard – Chapter 2, Appendix I

Homogeneity

- Minimum of 5 samples from the production run
- Analyzed in random order
- Includes a procedure to check for analytical drift

Homogeneity

- Samples are considered adequately homogeneous if the between sample standard deviation is less than or equal to 25% of the acceptance interval for the laboratories under test

Stability Requirement

- Stability testing to establish that for the period of the study the mean analytical value as determined after the study for each parameter falls within the 95% confidence interval calculated for the prior to shipment verification testing used to establish the assigned value
- Thank you appendix I

Stability Testing

- Begin after the close of the study
- Completed prior to publication of final reports
- 21 day limit

Stability Testing

- Analysis of a minimum of 3 samples
- Considered to be adequately stable if the absolute difference between the stability testing mean and the initial verification mean is less than or equal to 20% of the laboratory acceptance interval

Compliance

- PT study results
- Off the record comments
- Refusal to provide information

Due Diligence - Labs

- Question “Not Acceptables”
- “All data developed by the provider in support of verification testing, homogeneity testing, and stability analysis shall be provided to any laboratory participating in the program upon request after the close of the study.” – Ch. 2, App. B, 5
- File complaints with your state, NELAC PT Board and NIST/NVLAP

Due Diligence - Labs

- NELAC – Encourage the NELAC executive director and the PT Board to complete the PTOB/PTPA process ASAP
- Non-NELAC – Inform state of issues and request that they implement some oversight

Due Diligence - AAs

- Request data packages from providers
- Review limits and evaluations
- Encourage the process within NELAC and via the USEPA

Summary

- Sufficient requirements exist
- Not 100% compliance within the industry
- Protect yourself

Ensuring the Quality of Privatized Proficiency Testing Studies

Thank You

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US Army Engineer Research & Development Center

Development of Field Analytical Methods for Long Term Monitoring of Military Important Chemicals

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David E. Splichal
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Omaha, NE 68102

EPA 23rd Annual National Conference on Managing Environmental Quality Systems

US Army Engineer Research & Development Center

Long Term Monitoring Focus Area

- Long Term Monitoring (LTM) of groundwater :
  - Required component of closure on many DoD sites undergoing restoration.
  - All military services, other Federal agencies (e.g., DOE), states, and responsible parties share similar responsibility.
  - Costs associated with sampling and laboratory analysis over 10 years estimated to approach $500M.
  - Sample collection and laboratory analysis
    - 70% of the total monitoring cost.
    - 50% of the total investigation cost.

Long Term Monitoring Focus Area

US Army Engineer Research & Development Center

- Field analytical methods could reduce costs
  - Eliminate sample transport
  - Replace expensive fixed laboratory analytical costs

- Available field analytical methods may not be appropriate
  - Screening data produced
  - Delicate instrumentation unable to tolerate harsh conditions
  - Instrument operation requirements not compatible with field use
  - Inadequate for chemicals important to military

Focus Area Requirements

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- A(1.1.a) EQT Operational Requirements Document (EQT-ORD)
  - Reduce LTM costs from 25 – 50%.
  - Applicable to HMX, 1,3-DNB, NB, 3NT, 4NT, ClO_4^-, DU, propellants, pyrotechnics, and degradation products.
  - Definitive data.
  - 4 hour TAT.
  - Portable or *in situ*.
  - Easy to operate.
  - Capable of remote operation.
  - Comparable data to laboratory analysis.
  - Meets requirements of & accepted for SW-846.

Focus Area Project Delivery Team

US Army Engineer Research & Development Center

- Project Delivery Team: ERDC, AEC, and CEHNC.
  - Co-chaired by ERDC and AEC.
  - General oversight & dispute resolution by Environmental Technology Integrated Process Team (ETIPT).
- ERDC - S&T (BA1-BA3).
  - Dr. M. John Cullinane – Manager for S&T effort.
  - Dr. Denise MacMillan - S&T Focus Area Manager.
- AEC - T&E (BA4-BA6).
  - Mr. James Daniels Manager for T&E effort.
  - Mr. William Houser - T&E Focus Area Manager.
- DoD Coordination Group –
  - Effort Managers.
  - Focus Area Managers.
  - Rep from CEHNC, JUXOCO, SERDP/ESTCP.
  - Rep from other service.

Thrust Areas

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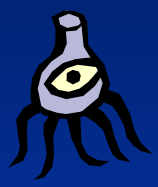
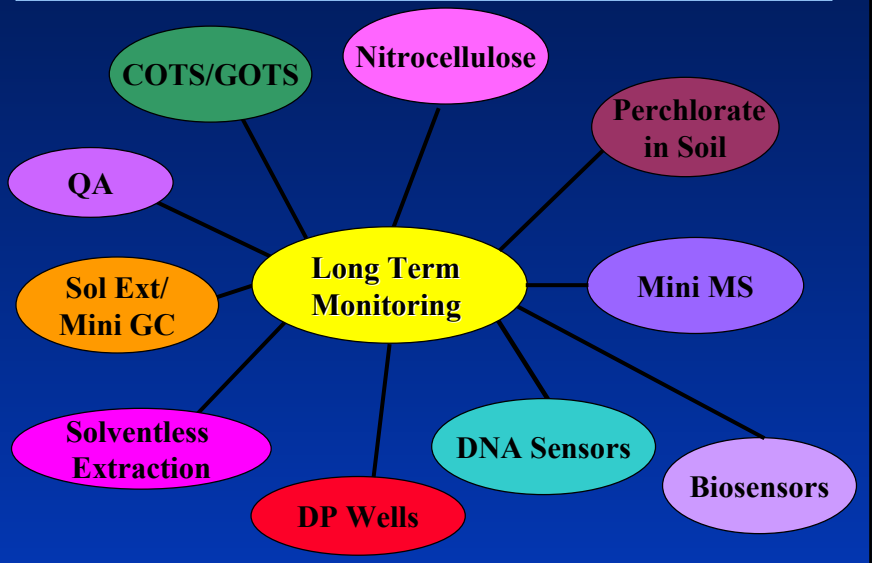
- Interim Improvements



- Leap Ahead Technologies
- Special Analytical Method Development

Long Term Monitoring Focus Area



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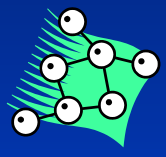
LTM Projects: Interim Improvements



- ✓ COT/GOTS
- ✓ QA Processes & Protocols
- ✓ Direct Push Wells & Samplers
- ✓ Solventless Extraction Technologies
- ✓ Solventless Extraction Technologies Interfaced to Miniature GC

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LTM Projects: Interim Improvements

US Army Engineer Research & Development Center

COT/GOTS

POC: Dave Splichal – Environmental Laboratory, ERDC

- ✓ 2004 ERDC Technical Report
  - ✓ Sampling Devices
  - ✓ Field Instrumentation – GC/MS
  - ✓ Sensors

- ✓ Applicability to LTM
  - ✓ Detection Limits
  - ✓ Quality Control
  - ✓ Cost Savings

LTM Projects: Interim Improvements

US Army Engineer Research & Development Center

QA Processes & Protocols

POC: Rich Meyer – Environmental Laboratory, ERDC

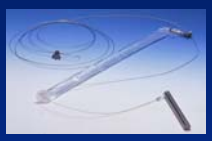
- ✓ Identify Essential QA/QC for Field Analytics
- ✓ Identify Reduced Cost Steps for Fixed Lab
- ✓ Evaluate Proposed Processes & Protocols
- ✓ 2004 ERDC Technical Report

Key Component of LTM Technologies is Ability to Generate Definitive Data

LTM Projects: Interim Improvements

US Army Engineer Research & Development Center

Solventless Extraction Technologies



POC: Dave Splichal & Denise MacMillan – Environmental Laboratory, ERDC

- ✓ Identify & Develop Solventless Ext Technologies
- ✓ Perform Lab & Field Studies
- ✓ Investigating use of Twister and SPME for MUCs
- ✓ Evaluation of Potential for On-Site Extraction

LTM Projects: Solventless Extraction

US Army Engineer Research & Development Center

Preliminary Results for On-Site Extraction of Explosives

Analyte	% Recovery	Method 8330 Control Chart, % Recovery
HMX	100	39-126
RDX	72	35-119
Tetryl	131	14-120
TNT	92	71-117
2,4-DNT	99	76-110

LTM Projects: Interim Improvements

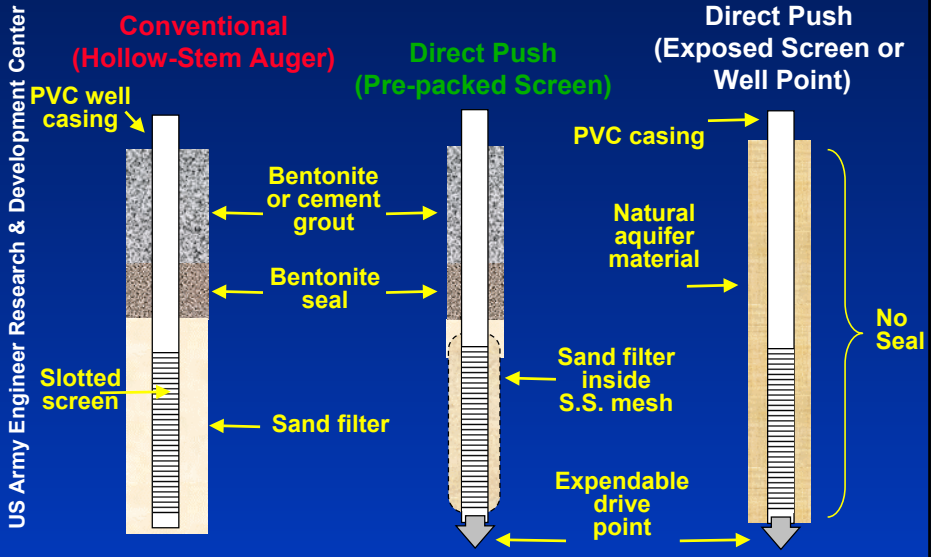
US Army Engineer Research & Development Center

Direct Push Wells & Samplers

POC: Louise Parker – Cold Regions Research Laboratory, ERDC

Direct Push Wells

US Army Engineer Research & Development Center



Promising Discrete-Interval Devices

US Army Engineer Research & Development Center

- Diffusion Sampler - Other polymer membranes

- Goal is to find a membrane/device that works for explosives
- Initial studies have focused on a jar-type sampler with open end covered with Nylon membrane
- Developed by Don Vroblesky (USGS)

Jar-Type Sampler Study

US Army Engineer Research & Development Center

Day 7	Control	Sampler	Difference
HMX	1.63	1.55	-4.8
TNB	14.6	14.2	-2.7
RDX	9.20	8.90	-3.3
1,3-DNB	0.635	0.619	-2.4
TNT	2.66	2.58	-3.2
2,4-DNT	0.095	0.092	-2.8
Day 35			
HMX	1.46	1.46	0
TNB	13.3	13.1	-1.5
RDX	8.18	8.22	+0.5
1,3-DNB	0.564	0.564	0.0
TNT	2.32	2.32	0.1
2,4-DNT	0.080	0.078	-2.6

Re-designed Hydrasleeve

US Army Engineer Research & Development Center

VOC Testing

and

Turbidity Evaluations

Snap Sampler

US Army Engineer Research & Development Center

- ✓ Spring activated
- ✓ No sample transfer
- ✓ VOCs, explosives, pesticides

LTM Projects: Interim Improvements

US Army Engineer Research & Development Center

Solventless Extraction Technologies Interfaced to Miniature GC

POC: June Mirecki and Dave Splichal – Environmental Laboratory, ERDC

- ✓ Develop Field Analytical Capability for Twister & SPME
- ✓ Perform Lab & Field Studies for Explosives Detection
  - ✓ Characteristic Spectra
  - ✓ Sensitive and Precise
  - ✓ Quality Control

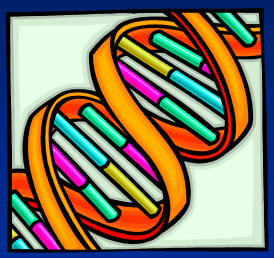
LTM Projects: Leap Ahead Technologies

US Army Engineer Research & Development Center

Catalytic DNA Sensors

POC: Don Cropek – Construction Engineering Research Laboratory, ERDC

Collaboration with Dr. Yi Lu, University of Illinois



- ✓ Specific – Reacts with a single chemical, reliable without false positives.
- ✓ Sensitive – Ultra-low concentration.
- ✓ Flexible – Detector for many different compounds.
- ✓ Convenient – Fast, small sensor array.

LTM Projects: Catalytic DNA Sensors

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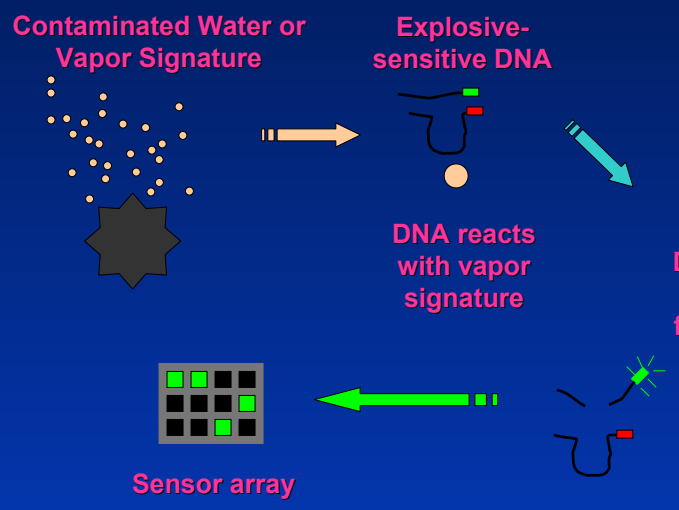

Land Mine

LTM Projects: Catalytic DNA Sensors

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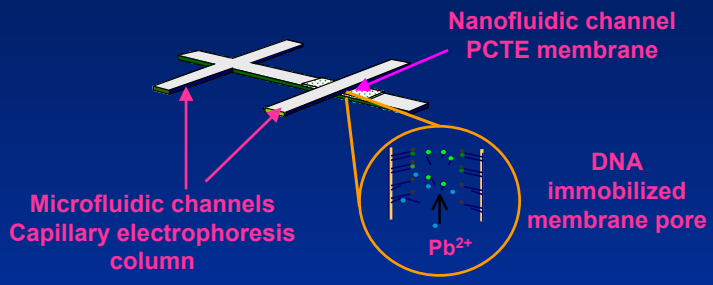
Nanofluidic Molecular Gate Membranes



Expanded view of the microfluidic channels and the nanofluidic molecular gate membrane.

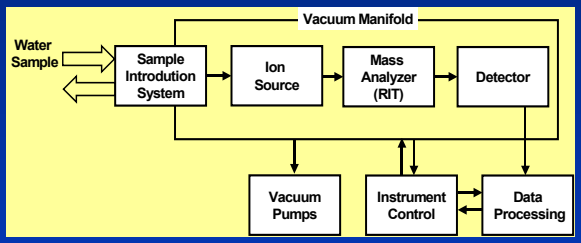
LTM Projects: Leap Ahead Technologies

US Army Engineer Research & Development Center

Miniature Mass Spectrometer

POC: Denise MacMillan – Environmental Laboratory, ERDC

Collaboration with Dr. Graham Cooks, Purdue University



LTM Projects: Leap Ahead Technologies

US Army Engineer Research & Development Center

Microfluidic Biosensors

POC: Shana Dalton and Denise MacMillan – Environmental Laboratory, ERDC

Biosensor: Sensor that uses biochemicals to detect chemicals.

Bioprobe: Sensor that detects biochemicals.

- ✓ **Develop Sensitive & Selective *in situ* Detection Capability for Exp with Antibody Capture Technology**
- ✓ **Identify & Develop Biosensor Technology for Perchlorate**

LTM Projects: Microfluidic Biosensors



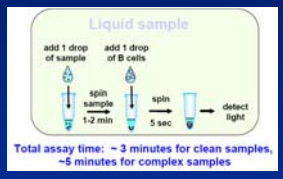
- ✓ Immunoassays with commercially available RDX and TNT antibodies immobilized on magnetic beads
- ✓ Expand the number of antibodies to MUCs
  - ✓ Developing antibodies to HMX and 2, 4-DNT with Strategic Biosolutions (~ 9 months / analyte)
- ✓ Collaborate with other laboratories currently developing immunoassay-based technologies

LTM Projects: Microfluidic Biosensors

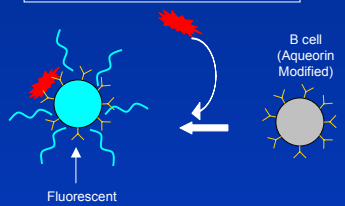
US Army Engineer Research & Development Center

CANARY (Cellular Analysis and Notification of Antigen Risk and Yields)

- ✓ Developed at MIT-LL
- ✓ Excellent for Biological Agents
  - ✓ *Bacillus anthracus* (anthrax)
  - ✓ *Yersinia pestis* (plague)
  - ✓ FMD (Foot and Mouth Disease) virus
  - ✓ *E. coli*
- ✓ Highly sensitive response in seconds
- ✓ Detection of Toxins – Developmental Stage



Total assay time: ~ 3 minutes for clean samples, ~5 minutes for complex samples



Source: Presentation at Federal Bio-Chem Detection Conference, Oct. 2003 by Peter Emanuel, PhD, Critical Reagents Program Director, JPE-CBD

Special Analytical Methods

US Army Engineer Research & Development Center

Nitrocellulose:

- ✓ Gun cotton, pyroxilin, ~12% N
- ✓ Occurs with nitroglycerin at firing points
- ✓ Differential solubility method under development

Perchlorate:

- ✓ Used primarily as a solid rocket fuel
- ✓ Sources include flares, airbags, fireworks, some nitrate-based fertilizers
- ✓ Through soils with little, if any, adsorption occurring
- ✓ Little literature evidence to support hypothesis
- ✓ Competes with iodine in thyroid – low action level expected

Special Analytical Methods

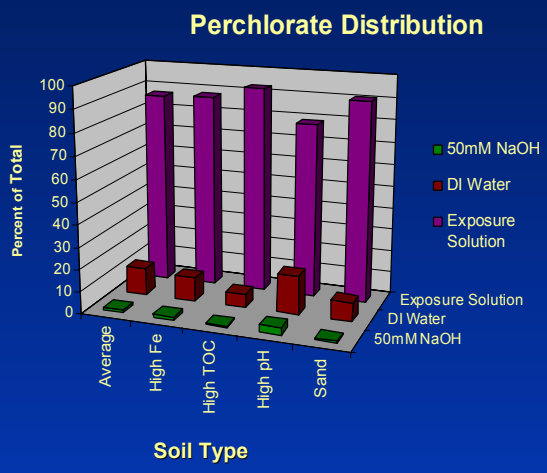
US Army Engineer Research & Development Center

- ✓ Soils utilized in the project
  - ✓ Average Soil
  - ✓ Sandy Soil
  - ✓ High Iron Content Soil
  - ✓ High pH Soil
  - ✓ High Total Organic Content Soil
- ✓ Experimental Conditions
  - ✓ Oxic
  - ✓ Anoxic
  - ✓ Controls
    - ✓ No Soil
    - ✓ No Perchlorate

Soil Characteristic	Average Soil [WES Reference]	Sandy Soil [Ottawa Sand]	High Fe Soil [Telleco Loam]	High pH Soil [Crot Sandy Loam]	High TOC Soil
UCS Classification	Clay (CH), Brown	SP	Sandy Clay (CL), Red	Sandy Clay (CH) Grey	
Total Ca (mg/kg)	1440	<20	416	59500	
Total Fe (mg/kg)	21100	103	51600	13500	
Total Mg (mg/kg)	2090	<25	1050	15000	
TOC (mg/kg)	5320	13.85	6033	4746	
Percent sand	0.5	97.6	30.9	49.1	
Percent Fines	99.5	2.4	69.1	50.9	
pH of 20% Slurry	4.97	6.2	4.28	9.73	

Special Analytical Methods

US Army Engineer Research & Development Center



Total (Perchlorate) = sum of the three different fractions

Preliminary Data (IC only)

- As expected, the majority of the perchlorate was recovered in the exposure solution, with only trace amounts detected in the final 50mM NaOH wash.
- There were no obvious differences between either soil type or oxygen conditions (oxic/anoxic).
- However, it is important to note that the values obtained have not been yet been corrected for any "carry-over" caused by the pore water that remains after centrifugation.

Acknowledgements

US Army Engineer Research & Development Center

Agnes Hindemith
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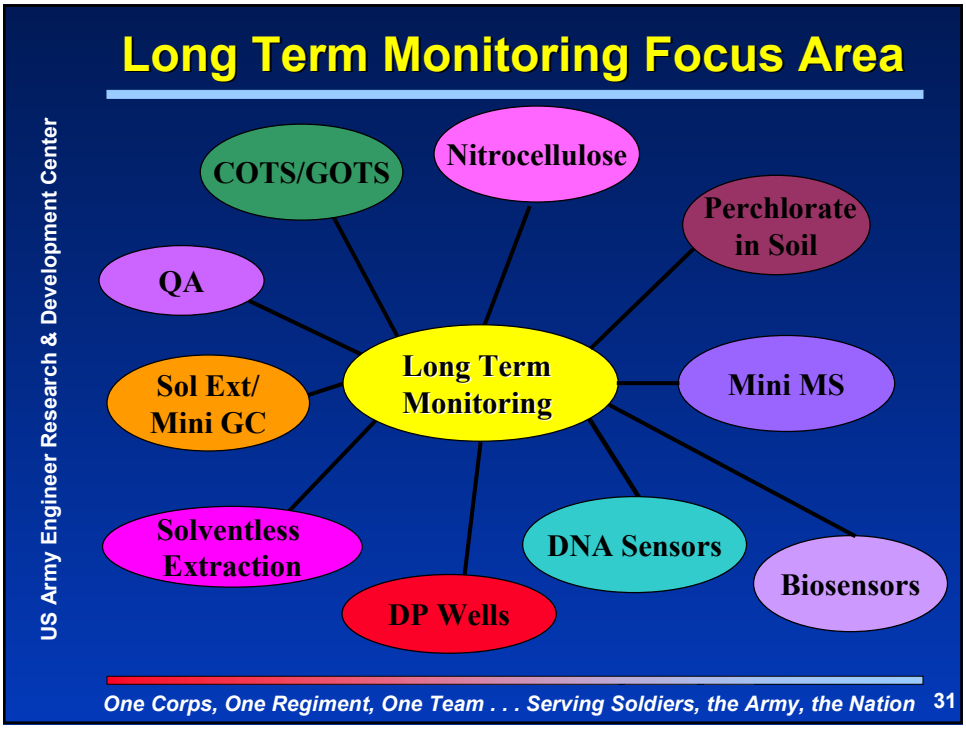
Lynn Escalon
John Shannon
Jim Elwell
Laura Percifield
Scott Waisner
Doug Taggart
Tony Bednar
Steve Schnitker
Anne Weathersby
Prem Arora


Long Term Monitoring Focus Area
US Army Engineer Research & Development Center
COTS/GOTS
Nitrocellulose
Perchlorate in Soil
QA
Long Term Monitoring
Mini MS
Sol Ext/ Mini GC
Solventless Extraction
DP Wells
DNA Sensors
Biosensors
One Corps, One Regiment, One Team . . . Serving Soldiers, the Army, the Nation
31

Tools of Quality

Measuring and reporting on information quality as a products

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PRIOR
EPA Quality Staff
EPA ORD National Risk Management Research Laboratory
TechLaw CEAT w/ EPA National Enforcement Investigations Center

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3

THANK YOU

Quality staff
Diann Sims
You!!!

4

Overview

- *Tools*
- Information
- Measures
- The what vs. the how of information
- Value
- Who's information is it anyway?

5

Audience participation

I can't do this alone!!!

I'm only one man Regis Philbin

6

THE BASICS….

The basics about information

7

Your information

- Do you have information?
- Do you value your information?
- Does it support your success?
- Do you know the content is good? How? What is good?
- Do you know the dissemination is good? How? What is good?

8

Your information –
what is good?

- Name it
- Categorize it
- Define it
- Measure it

9

INFORMATION PRODUCTION

To understand information quality….

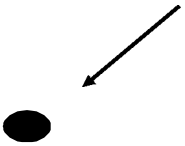
let's look at the

features of information

10

What are the relationships of the features to the processes?

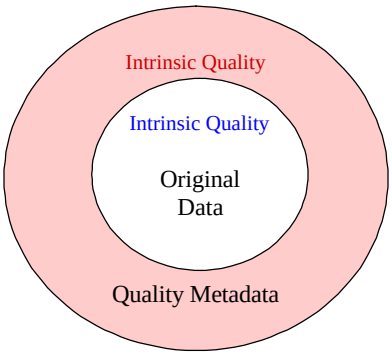
Let's start with a project view and consider a single data point!



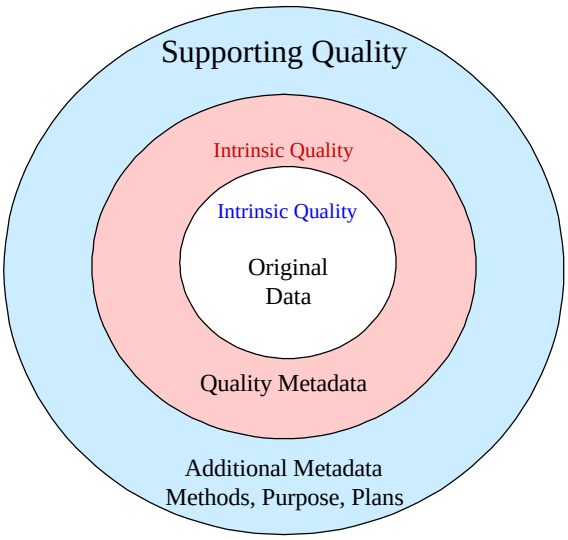
11

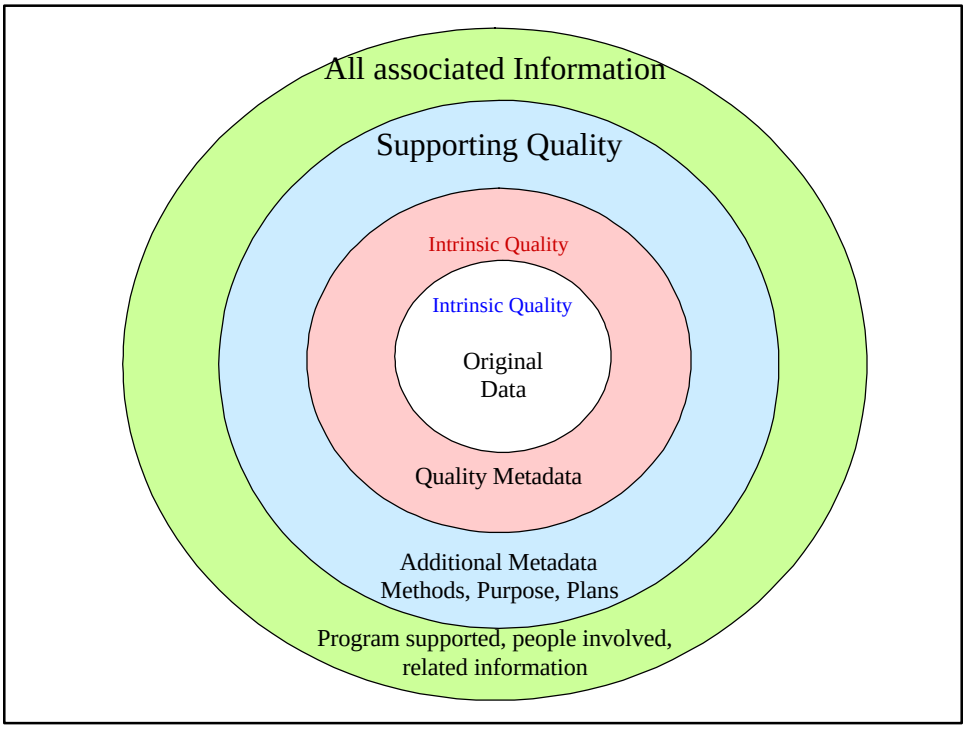
One small
"data package"
This only contains the original data

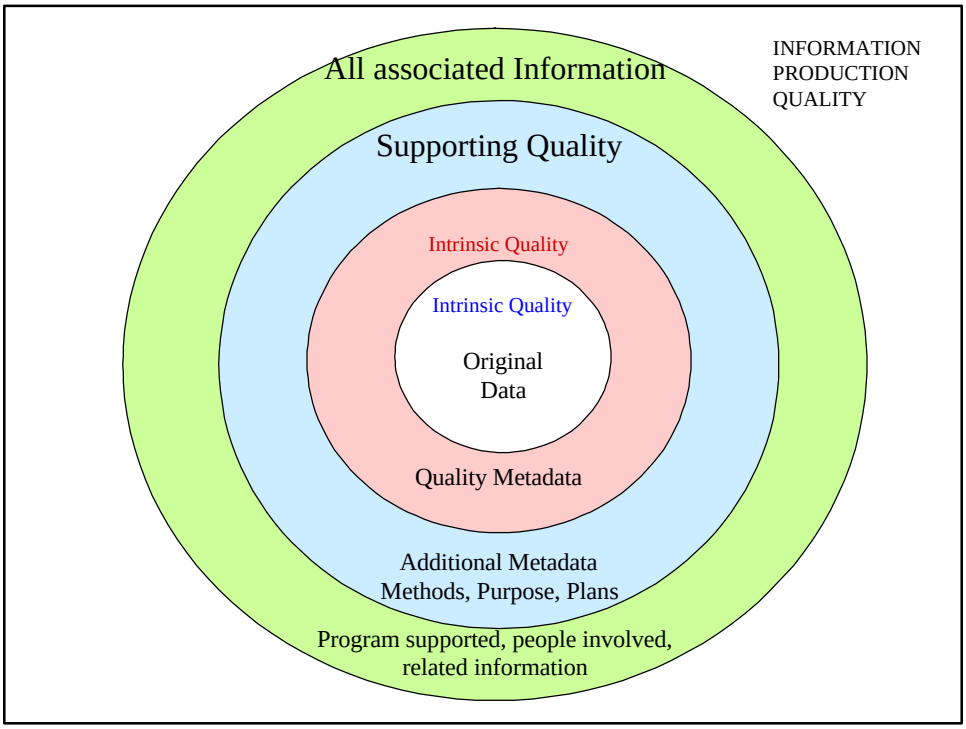
Some data, which specifically describes quality features of the data may accompany the original data to form a larger data package.



These data and the "quality metadata" represent quality that is "intrinsic" to the data that is central to the work.

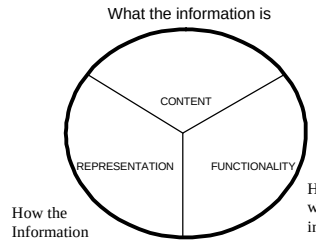



All associated Information
Supporting Quality
Intrinsic Quality
Intrinsic Quality
Original
Data
Quality Metadata
Additional Metadata
Methods, Purpose, Plans
Program supported, people involved,
related information


INFORMATION
PRODUCTION
QUALITY
All associated Information
Supporting Quality
Intrinsic Quality
Intrinsic Quality
Original
Data
Quality Metadata
Additional Metadata
Methods, Purpose, Plans
Program supported, people involved,
related information

Tier III Higher Level Product Features

- Transparency
- Usefulness
- Accessibility



Tier II
Information Dimensions

All THREE major aspects of information quality are in turn affected by processes:

CONTENT
-Science process
-Administrative process

FORMAT
-Data representation design
-Web design and standards

FUNCTIONALITY
-IT design and standards
-Software design

Tier I
Associated processes

- Science
- Administrative
- IT & hardware
- Software

17

WHAT'S UP IN QUALITY

- Information Integrity Workgroup, American Society for Quality

- International Association for Information and Data Quality (IAIDQ), an affiliated special interest group of the Data and Management Association (DAMA)

18

WHAT'S UP IN QUALITY

•American Society for Quality ANNUAL QUALITY CONGRESS, May 2004 Toronto
www.asq.org

•ASQ Energy and Environmental Division Meeting meeting in Orlando, Florida, September 2004

19

THE END

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10 LAWS

The ten laws of managing information as product

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Quality staff
Diann Sims
You!!!

4

Overview

- **Everything changes, but……**
- **The value of information**
- **Information as a product**
- **The laws**
- **Talk is talk**
- **How to use the laws**

5

Everything changes, but it remains the same……

Customer satisfaction or dissatisfaction

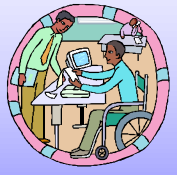
- Product is always product (even when it is a service)
- Quality is always quality
- Management is always management
- Information is always information

What is different is *how much* and *how fast* you can create and disseminate information.

6

The *value* of information

What gives information value?



- The right information, at the right time, in the right format!!!

- Both the production (content) and the dissemination aspects of information are *information quality*.

7

Consider the value……..

- **The correct and accurate information delivered late may be of little or no value.**
- **The wrong information delivered on time may not be of value.**
- **The delivery of information in the wrong format may also be of no value.**

8

information is ubiquitous

If you value the information, then you should have a process to control the quality of both the production and delivery of the information.

Treat the information as a product.

9

The 10 laws of managing information as a product

10

LAW 1: *You must have information about your information in order to manage your information as a product.*

Information status - management systems, strategic planning, the technical design, and the delegation of authority for information and information processes, must include a process to capture and report on the status of information in order to allow you to manage the information as product. This status information is needed to know if and to what degree the processes that you have put in are working or are not working. That information needs to be as independent as possible.

11

LAW 2: *You must have a common language in order to discuss the management of information as a product.*

Common language - you need a common language to plan and discuss the management of information as a product. Because disciplines have related terminology, you need to either develop a common language or provide some roadmap between the discipline language to facilitate communication about the information. Agreement on the language will facilitate communication, assist in standardizing discussions about status, and ensure that planning and implementation processes are described to the degree necessary.

12

LAW 3: *You must understand the nature of information in order to manage information as a product.*

Information/data *properties* - the nature of information is important if you view as either a product or a resource because information is different that other resources in both how you produce and distribute it as a product and in how you access and interact with it as a resource. The *properties* of information in a large part determine both concerns and what is valued about information as a product or resource. Some common properties that give information value include *copyability*, *unconsumability*, *and transferability*..

13

LAW 4: *You must identify the specific information and information processes that are of interest to you in order for you to manage information as a product.*

Information of interest - focusing on the specific information and information processes that you value will enable you to plan more effectively. General planning to simply improve information will not provide you with a target-rich environment. Planning must focus on a clear objectives.

14

LAW 5: You must identify what you value about information in order to manage information as a product.

Information features - you must be able to identify and describe the *what* and the *how* of the information and information processes that are of value to the organization. Features can simply be thought of as a collection of adjectives and the features can be categorized into several different schemes. One scheme is to view the features in terms of three basic dimensions:

- **content** - these are the features that describe the *what* of the information, whether it is financial information or scientific information. Example include *correctness, completeness, relevance*, etc.
- **format** -these are the features that concern the manner in which the information is captured, stored, or presented. For example, geographic information may be in either tabular or graphic format. For graphic format, one example feature is *granularity*.
- **functionality** - these are the features that have to do with the *how* of the information, how it moves, how it is accessed, how it is presented and they are often therefore associated with technological processes. Example features include *timeliness of data availability, accessibility*, etc.

15

LAW 6: You must be able to measure what you value about information in order to manage information as a product.

Measures - you must be able to express features in terms of measures that describe what it means to fully or partially have the value that your desire. For example, *timeliness* can be measured either by days, minutes, hours, etc. or it can be measure by "number of failures that information was received on time."

16

LAW 7: You must be prepared to set expectations about your measures in order to manage information as a product.

Acceptance criteria - knowing what you value and how to measure is a good start; however, establishing your expectations is necessary in order to manage information as product. You must be able to express when your expectations have been met. For example, is it OK that a database is 80% +/- 15% correct or does it need to be 99.95% +/- .05% correct? Identify what you value, what you measure, and what your criteria are will help you to determine how to report status as described in Law 1.

17

LAW 8: Your strategy for managing information must be in alignment with the strategy for the enterprise in order to manage information as product.

Information strategy for quality - must be consistent with the information strategy and both must be consistent with the strategy for the organization which flows from the vision and mission of the organization. Great quality data and information that have nothing to do with what the organization or its customers need is of little or no value. Efforts to improving the quality of something without understanding how it will help the overall organization is a questionable practice.

18

LAW 9: You get the information you plan for.

Quality planning - planning for the quality of information is critical to ensuring the quality of information production and distribution. It is not enough to know what it is, how to measure it, and how good you want it to be. If you do not plan to achieve information of a certain value, we will not know the value of the information that you do have.

19

LAW 10: You need to report the quality of the information and progress of quality affecting processes to senior management and staff.

Reporting - communicating the quality of the information and progress in quality processes allows both managers and staff to take the appropriate actions. They must be part of your process.

20

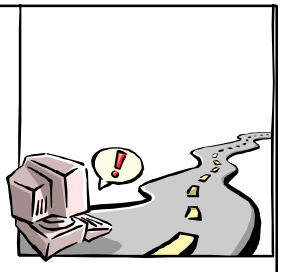
Talk is talk

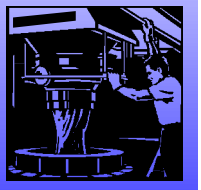
Talking information improvement =

…… if you are planning to improve the quality of the production and delivery of information AND you do not have processed in place to identify what you value and how you will measure the improvement THEN you are talking quality.

21

How can I use the laws?





•What is the current status of your organization in terms of the laws?
•Can you provide resources to conduct a preliminary assessment?
•Can IT and other resources be combined?
•Can you forecast savings for the organization?
•Conduct a meeting with management to discuss the issues?
•Develop a quality strategic plan to improve the quality system?
•Develop a straw model of an approach to consider changes to start a dialogue with management and staff?

22

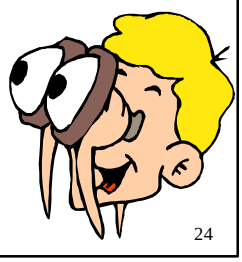
How can I use the laws?

- **Collect the existing terminology from each discipline, make a dictionary.**
- **Identify established measures (quality metrics) and verify the usefulness to management and staff.**
- **Review organization's mission and vision, validate or create the link to the information product of the organization.**

23

FEEDBACK

Do you have any suggestions to address the 10 laws or other priorities in ensuring information quality?



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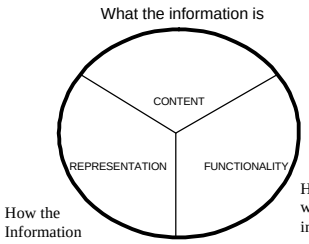
- Usefulness
- Accessibility



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THE END

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ANSI/ASQ E4-2004 Overview

Gary L. Johnson
U.S. EPA
Research Triangle Park, NC 27711

April 2004
EPA National Conference on Managing Environmental Quality Systems

Today We Will

- Briefly describe ANSI/ASQ E4-2004 and its benefits as a QMS standard.
- Outline the ANSI approval process.
- Provide an overview of revised standard and what has changed.
- Summarize the status of standard.

What is ANSI/ASQ E4-2004?

- An consensus-based American National Standard for quality management systems for environmental sector programs.
- Provides specific QMS specifications for:
  - Quality Management practices
  - Environmental data collection and use
  - Design, construction, and operation of engineered technology
- Provides guidance on the use of E4, including going beyond the minimum specifications.

ANSI/ASQ E4-2000 Background

- Originally ANSI/ASQC E4-1994:
  - Developed by ASQ Energy and Environmental Division (EED)
  - Derived from several existing standards and protocols (ASME NQA-1, ISO 9001, EPA QMS guidance)
- Adopted as basis for U.S. EPA Quality Policy in 1998.
  - EPA Order 5360.1

ANSI / ASQ E4-2000 Background continued

- Added to Federal Acquisition Regulations in 1999.
  - 48 CFR Part 46
  - "High Level" Quality Assurance standard
- E4 adoption as a sector-specific standard for environmental programs includes:
  - Other Federal departments and agencies
  - State and local governments

American National Standards

- American National Standards are:
  - Developed by ANSI-approved Standards Development Organizations
  - Subject to extensive consensus review and public comment
  - Approved by ANSI for up to five years.
- ANSI rules require periodic review to:
  - Re-authorize the standard without change
  - Withdraw the standard
  - Revise the standard.

ANSI Review of E4

- ANSI/ASQC E4-1994 was reviewed per ANSI rules.
  - ASQ EED formed the E4 Work Group
  - Survey of users
  - Determined that modest revision was needed.
- Consensus Body was the ANSI ASC Z1 Quality Management Subcommittee.
- E4 Work Group prepared revised text.

ANSI Review of E4

- Z1 and Public Reviews
  - Public reviews produced few comments.
  - Z1 reviews produced several improvements to the standard.
- ANSI approval of revised standard completed on February 4, 2004.

Objectives of E4 Revision

- Few substantive technical changes.
- Simplify structure and presentation of requirements and guidance.
- Align E4 with ISO 9001:2000 to the extent practicable.

Approach to Revisions

- Change the presentation format
  - Use ISO style and format
  - Use ISO 9000:2000 terms and definitions where possible
  - Separate guidance from specifications and place in an Annex
- Provide a cross reference to ISO 9001:2000 for consistency and alignment.
- Incorporate “lessons learned” from 1994 E4 implementation and use.

Structure of ANSI/ASQ E4-2004

Foreword

0 Introduction

1 Scope

2 General Principles and Applications

3 Normative References

4 Terms and Definitions

5 Management Systems

6 Collection and Evaluation of Environmental Data

Structure of ANSI/ASQ E4-2004

7 Design, Construction and Operation of Environmental Technology

Annex A Terms and Definitions

Annex B Guidelines on the Use of ANSI/ASQ E4

Annex C Crosswalk between ANSI/ASQ E4 and ISO 9001

Foreword

- Provides general background on ANSI standards.
- Credits those responsible for standard.
  - ANSI ASC Z1 Committee
  - ASQ Energy and Environmental Division
  - E4 Work Group
- Indicates that this edition replaces the 1994 version in its entirety.

0 Introduction

- Provides general statement on purpose of E4 standard.
  - QMS for environmental programs
  - Minimum set of requirements
  - Provides for nonmandatory guidelines
- Compatibility with other management systems.
  - ISO 9000 series
  - Not an EMS standard
- Not an auditable part of the standard.

1 Scope

- Brief statement of the intent and organizational applicability of the standard.
  - E4 is a specification or requirements standard
- Emphasizes flexibility and broad range of users.

2 General Principles and Applications

- Brief statement of the general principles used:
  - Quality system as a framework for QA and QC.
  - Planning, implementation, and assessment.
  - Use of “graded approach.”
  - Retains modular design from 1994 version.
- Notes environmental programs to which E4 may be applied.

3 Normative References

- Identifies other documents whose provisions are included in ANSI/ASQ E4-2004 by reference.
- There are two normative references:
  - **ISO 9000:2000 QMS Vocabulary**
  - **ISO 14050:1998 EMS Vocabulary**

4 Terms and Definitions

- Provides for additional definitions not specifically covered in normative references or Annex A.
- Key terms include:
  - Environmental data
  - Environmental data operations
  - Environmental processes
  - Environmental programs
  - Environmental technology

5 Management Systems (Part A)

- Provides criteria for establishing and maintaining an effective quality system.
- Quality management elements must be used with Clause 6 or Clause 7 requirements to complete the QMS.

5 Management Systems (Part A) continued

- Quality management elements include:
  - Management and organization
  - Quality system and description
  - Personnel qualification and training
  - Procurement of items and services
  - Documents and records
  - Computer hardware and software
  - Planning
  - Implementation of work processes
  - Assessment and response
  - Quality improvement

5 Management Systems (Part A) continued

- Quality management elements:
  - Define management roles and responsibilities
  - Require a QA Manager who reports to top management and who has organizational independence
  - Specify functional responsibilities within the organization.
  - Require a Quality Management Plan.
  - Require periodic management review.

6 Collection and Evaluation of Environmental Data (Part B)

- Clause 6 elements include:
  - Planning and scoping
  - Design of data collection operations
  - Implementation of planned operations
  - Assessment and response
  - Assessment and verification of data usability
- Few changes from 1994 version.

7 Design, Construction, and Operation of Environmental Technology (Part C)

- Clause 7 requirements include:
  - Planning
  - Design of systems
  - Construction/fabrication of systems and components
  - Testing and operation of systems
  - Assessment and response
  - Verification and acceptance of systems

Annex A Terms and Definitions

- Expanded list of related terms and their definitions.
- ISO 9000:2000 definitions used where applicable.
  - Helps to achieve compatibility with ISO 9001.

Annex B Guidelines on the Use of ANSI/ASQ E4

- Provides nonmandatory guidelines to augment specifications given in this standard.
- Guidance is grouped as:
  - General use of the standard.
  - Guidelines for management systems.
  - Guidelines for collection and evaluation of environmental data.
  - Guidelines for the design, construction, and operation of environmental technology

Annex C Crosswalk Between ANSI/ASQ E4 and ISO 9001

- Provides crosswalk between this standard and ISO 9001:2000.
- Identifies equivalent clauses in each standard.
- Shows that E4 addresses all of the requirements of ISO 9001.

Summary

- ANSI/ASQ E4-2004 is an approved American National Standard.
- ANSI/ASQ E4 is a recognized ISO 9001 equivalent standard.
  - Registrar Accreditation Board (RAB)
  - E4 audits are acceptable for RAB QMS Auditor and Lead Auditor certification
- Next steps include revision of EPA policy documents to adopt current version.

Guidance and Tools for Implementing Environmental Quality Systems

Mike Carter, U.S. EPA, Federal Facilities Restoration and Reuse Office

1

Purpose

- Introduce guidance and regulatory drivers for implementing environmental quality systems
- Introduce existing electronic tools for QA
- Discuss how guidance and tools can be integrated and where there are still gaps

2

Drivers for Creating Guidance and Tools

- **Data quality that meets needs**
- **Savings in costs/time for repeated work, reaching agreements on site closure**
- **Information Quality Guidelines**

3

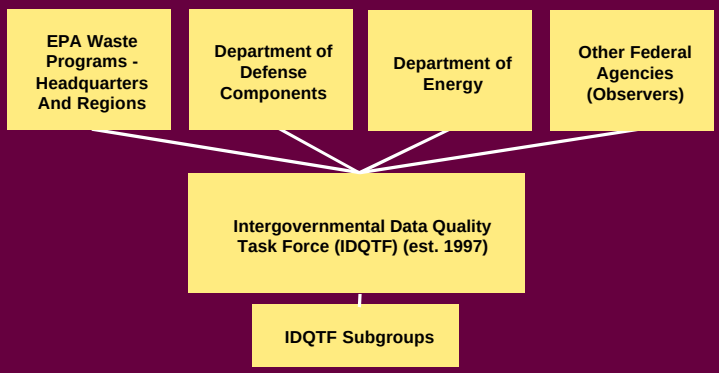
Information Quality Guidelines

- ***Guidelines for Ensuring the Quality, Objectivity, Utility, and Integrity of Information Dissemination by the Environmental Protection Agency*** **(October 2002)**
- **EPA's policy and procedural guidance for ensuring and maximizing the quality of information it disseminates**
  - Mechanism to correct information disseminated by the EPA
  - General assessment factors for evaluating the quality of scientific and technical information

4

Intergovernmental Data Quality Task Force (IDQTF)

- Formed in 1997 to address inconsistencies and deficiencies within quality systems
- Chaired by Director of Federal Facilities Restoration and Reuse Office (FFRRO)



5

Uniform Federal Policy for Implementing Environmental Quality Systems (UFP-QS)

- A guide for documenting and implementing a quality system
- Based on ANSI/ASCQ E-4
- Formally adopted for hazardous waste by EPA, DoD, and DOE (Jan. 2003)

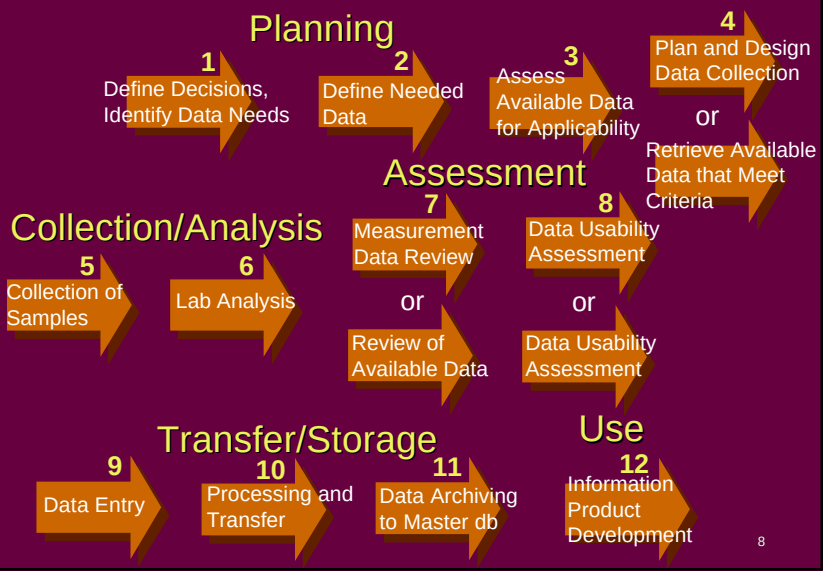
6

UFP-QS Implementation

- Depends on individual organization
- May require development of new QMP or evaluation of existing quality system
- Requires oversight functions

7

Quality System Should Link All Data Collection and Use Steps Together



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Electronic QA Tools

- Many tools that aid in planning and implementing quality in projects exist or are currently under development
- Quality system must support project implementation
  - Make sure appropriate tools are available
- Concern is being able to link tools and spread word about their availability

9

Visual Sample Plan (VSP)

- Allows user to define an optimal, technically-defensible sampling scheme
  - Balances uncertainty with project resources
- Supports many common sample designs: simple random, grid and transect, ranked set, adaptive cluster, etc.
- Menu driven with extensive help features
- http://dqo.pnl.gov/vsp

10

Field Environmental Decision Support (FIELDS)

- Provides integrated environmental decision making through a suite of sample design, database query, geospatial modeling, and analysis (human health and ecological risk assessment) modules
- Implemented in ArcView
- Link to VSP (import and export)
- Menu-driven, requires competence in ArcView
- www.epa.gov/region5fields/

11

Spatial Analysis and Decision Assistance (SADA)

- Stand-alone, integrated set of spatial analysis, statistical risk assessment, and second-round sampling decision tools
- Provides data visualization in two or three dimensions
- Supports various geospatial interpolation methods and human health and ecological risk assessment
- Menu-driven, requires understanding of technical basis of tools
- www.tiem.utk.edu/~sada/

12

Staged Electronic Data Deliverable (SEDD)

- Provides framework for specifying standardized electronic data deliverable formats
  - Document type definitions (DTDs) developed using XML
- Contains comprehensive Data Element Dictionary with pre-defined data elements
- Requires familiarity with XML
- www.epa.gov/superfund/programs/clp/sedd.htm

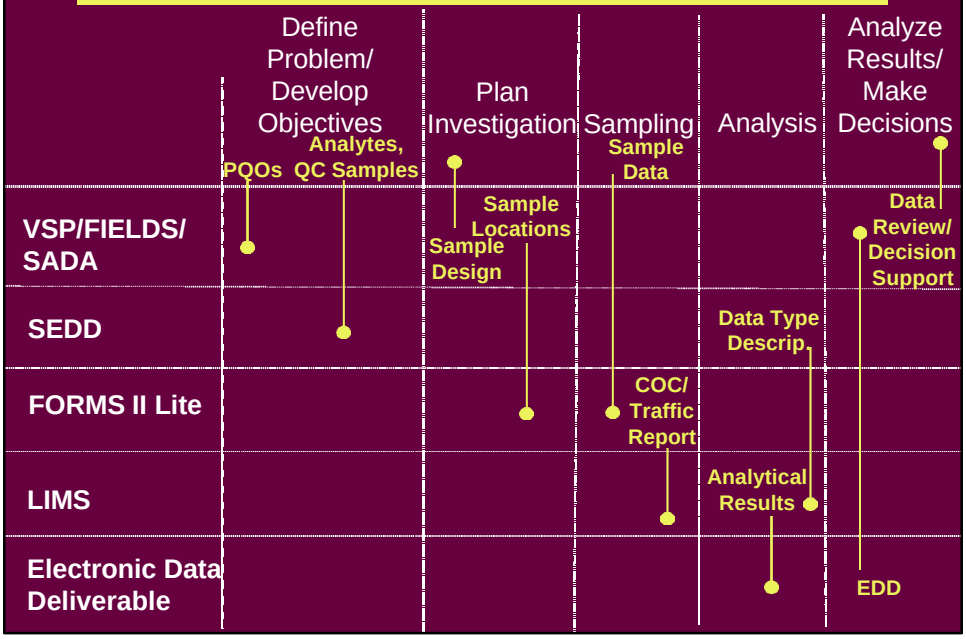
13

Field Operations and Records Management System (FORMS) II Lite

- Simplifies and accelerates the sample documentation process in the field
- Users can export sampling data electronically, reducing transcription errors
- Mandated for CLP
- Step-by-step wizard that allows customization of labels and reports
- FORMS II LIMS allows exportation to lab's system
- F2lite@dyncorp.com

14

Electronic Tools Linkages



Questions?

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16

The Approach of the Uniform Federal Policy on Environmental Quality to Quality Assurance Project Plans

Robert Runyon, U.S. EPA, Region 2

1

Two-part Quality System

- **Program level**
  - *Uniform Federal Policy for Implementing Environmental Quality Systems* (UFP-QS)
- **Project level**
  - *Uniform Federal Policy for Quality Assurance Project Plans* (UFP-QAPP)

2

Purpose

- Introduce the UFP-QAPP
- Describe the framework and organization of the Manual
- Highlight areas of focus
- Introduce implementation tools (workbook, QA/QC Compendium, training)

3

Benefits of Approach

- Stresses team-based project planning and assessment with participation from all relevant disciplines
  - Chemists, risk assessors, etc.
  - The right people providing technical input at the right time
- Requires problem and objectives of project be defined before sampling begins
  - Defines how much, what type, and level of quality (e.g., DQO, systematic planning outputs)
  - Provides criteria for data usability assessment

4

Basis of UFP-QAPP

- **ANSI/ASQC E-4 Part B**
- **EPA QA/R-5 and QA/G-5**
- **Region 1 QAPP Guidance**
  - As starting point
  - Organized around four major QAPP elements and use of worksheets
- **Work of IDQTF consensus workgroup**
  - Representatives from EPA headquarters and Regions, DoD and DOE

5

Format

- **Follows Systematic Planning Process (SPP)**
  - Formal DQO Process (EPA QA/G-4) or other
- **Fill-in-the-blank worksheets for each QAPP element**
- **Allows for graded approach**
  - Amount of documentation and detail will depend on complexity and scope of project

6

Generic vs. Project-specific QAPPs

- **Generic QAPP: Overarching plan applicable to**
  - Single site with multiple activities (e.g., soil, groundwater and surface water sampling)
  - Single activity at multiple sites (e.g., same type of air monitoring at several Air Force bases)
- **Project-specific QAPP**
  - Applicable to projects of limited scope and time
  - Can supplement generic QAPP for specific site or activity

7

QAPP Element #1: Project Management and Objectives

- **Project organization**
  - Establish project team
  - Define roles and responsibilities
  - Outline communication pathways
- **Project planning/scoping**
  - Problem definition
  - Establish project quality objectives (PQOs) and measurement performance criteria (MPC)

8

PQOs and MPC

- **PQOs define the type, quantity, and quality of data needed to support proper environmental decisions**
  - Presented as qualitative and quantitative statements
- **MPC are acceptance limits that will be used to judge whether PQOs are met**
  - Determined for each matrix, analytical group, concentration level
  - Relate to DQIs (accuracy, precision, etc.)

9

QAPP Element #2: Measurement and Data Acquisition

- **Defines all sampling and analysis procedures***
  - Sampling design and rationale
  - Sample collection, equipment cleaning and calibration, field documentation
  - On-site (field) and off-site analytical methods
  - QC samples
  - Project documentation and records

***SOPs, method manuals, etc. may be attached to QAPP or clearly referenced**

10

QAPP Element #3: Assessment and Oversight

- Ensure planned activities implemented as described in QAPP
- Establish planned assessments (type, frequency, responsibilities)
- Describe how deficiencies will be communicated and corrected
- Define content, frequency, and responsibilities for QA Management Reports

11

QAPP Element #4: Data Review

- Process of examining and evaluating data to ensure they meet data quality requirements of the project
- Same intention as EPA QA/G-8, but slightly different definitions
- Allows for streamlining, when appropriate
- Some new concepts
  - Includes sampling component in data review
  - Includes usability assessment by project team

12

Data Review Steps

Process Term	Scope	Data Review Step
Verification	•Sampling* •Analysis	I. Completeness Check
Validation	•Sampling* •Analysis	II a. Check compliance with method, procedure, and contract requirements II b. Compare with MPC from the QAPP*
Usability Assessment*	•Sampling* •Analysis*	III. Assess usability of data by considering PQOs and the decision to be made*

*Expansion of current practice

13

UFP-QAPP Workbook

- Part 2A of UFP-QAPP
- Blank worksheets and brief instructions
- To be used in conjunction with Manual
- Ensures consistent content and presentation of information
  - Expected to streamline review
- Worksheets are optional and may be modified as necessary

14

QA/QC Compendium

- Part 2B of UFP-QAPP
- Selects value-added QC requirements based on cost/ benefit analysis
- Sets minimum QC requirements for planning through data review, for Superfund projects
  - May need additional QC for certain projects

15

QA/QC Compendium: QC Samples

- Assesses QC samples based on their respective results' contribution to DQIs
- Establishes minimum requirements for types of QC samples
- Encourages use of batch-specific PT samples

16

Example QAPPs

- **Part 2C of UFP-QAPP**
- **Demonstrates use of worksheets and applicability to different types of projects**
  - Fish Tissue QAPP
  - Ordnance and Explosives (OE) QAPP
- **Still undergoing revision**

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Implementation

- **UFP-QAPP is voluntary consensus policy**
  - Once adopted by Federal department, agency, or program, use is mandatory within that organization
  - Each participating Federal department, agency, or program must develop its own implementation plan
- **Applies to initial and revised versions of QAPP**
  - Not retroactive to previously approved QAPPs

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Training

- **3-day course currently being given to EPA Regions**
  - Through CECOS
  - Regions 3, 4, 8 and 9 complete
  - Region 5 next week
  - Remaining Regions sometime this year

19

Next Steps

- **Send Manual, Workbook, and QA/QC Compendium to EPA, DoD and DOE for concurrence in late spring**
- **Continue implementation and training efforts**

20

To Download Documents:

http://www.epa.gov/swerffrr/documents/intergov_qual_task_force.htm

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21

Environmental Information Exchange Network

Using the State - EPA Exchange Network to Improve Data Quality and Timeliness

April 16, 2004

Patrick Garvey

EPA Director
Network Steering Board

State/EPA Information Trends

- High demand for access to environmental information among partners
- Current stove-pipe approaches to information exchanges are inefficient and burdensome
- States modernizing information systems and migrating away from use of EPA national systems
- Use of integrated information technologies and approaches is on the rise

State/EPA Shared Vision

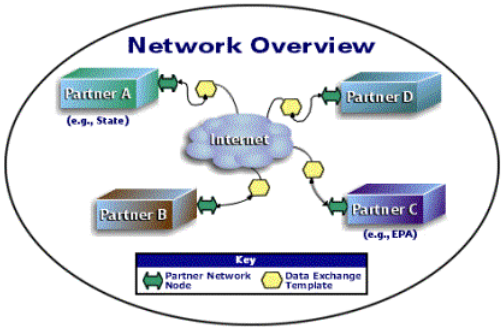
The States and EPA are committed to a partnership to build locally and nationally accessible, cohesive and coherent environmental information systems that will ensure that both the public and regulators have access to the information needed to document environmental performance, understand environmental conditions, and make sound decisions that ensure environmental protection.

IMWG Develops Exchange Network

The IMWG focused on the issue of "how" data is exchanged between partners (states, EPA, local, industry, other agencies)

- June 2000 – IMWG prepared "*Shared Expectations of the State/EPA Information Management Workgroup for a National Environmental Information Exchange Network (the Network)"*
- July 2000 – IMWG chartered a Network Blueprint Team to prepare the conceptual design for the Network
- October 2000 – IMWG Blueprint Team Initial Report describes the Exchange Network Concepts
- February 2001 - IMWG Blueprint Team Update and commissioning of an Interim Network Steering Group to develop Implementation Plan
- 2002 Exchange Network Implementation plan finalized
- 2002 Network Steering Board (NSB) chartered to implement the Exchange Network
- Fall 2003 – First data flow from State to EPA using the Network (Beaches)

What is the Exchange Network?



An Internet and standards-based method for exchanging environmental information between partners.

Exchange Network Foundations

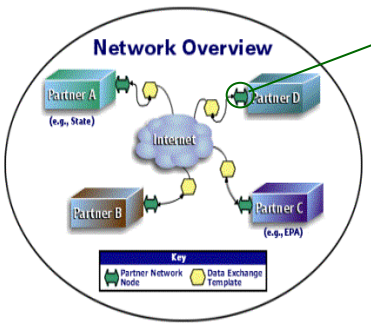
- Data standards are incorporated
- Partners agree on exchange data type, frequency, and method
  - Trading Partner Agreements
  - Registered XML schema
  - Partners exchange data over a secure network via each partner's data transfer point, or "Node"

Focus on Data Quality

- Key principal is to foster and improve the sharing of quality data. The EN supports this by:
  - Incorporating data standards
    - Coordination and direct linkages with State/EPA Environmental Data Standards Council (EDSC)
  - Validating registered XML Schema
  - CDX performs data quality checks

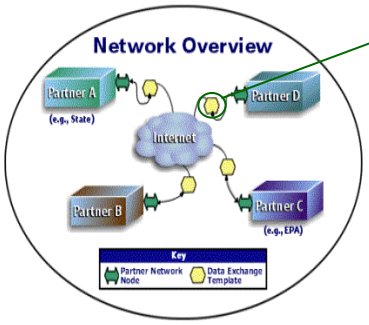
  The focus is to automate data sharing to allow for more time to be spent on data analysis and usage to make sound decisions!

Data Transfer Nodes (Web Services)



- Nodes
  - Hardware and software used to exchange information on the Network
  - Use the Internet, a set of protocols, and appropriate security to respond to authorized requests for information
  - Send the requested information in a standard format, XML
  - Each partner has only one Node

Data Exchange Templates/ XML Schema



- Data Exchange Templates
  - Describe format of data being exchanged
  - Consist of XML schema
  - Draw upon data standards
  - Potential to reuse XML schema modules

Schema are developed for each exchange type (e.g., Discharge Monitoring Report data)

Trading Partner Agreements (TPAs)

- TPAs are made between exchange partners (e.g., State and EPA)
- Identify data exchange frequency
- Identify exact data types/fields exchanged

TRADING PARTNER AGREEMENT

Between the Nebraska Department of Environmental Quality hereinafter referred to as NDEQ and the U.S. Environmental Protection Agency Region VII acting as a representative for the U.S. Environmental Protection Agency and hereinafter referred to as EPA for their participation in sharing data as part of the Facility Identification Integration Activities. The use of the term Agency will refer to both partners.

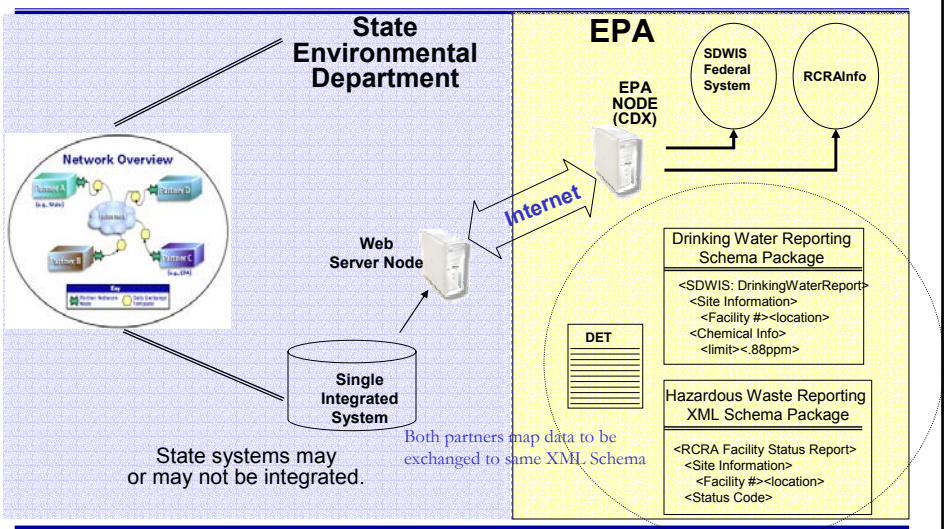
I. PURPOSE

The purpose of this Trading Partner Agreement (TPA) is to identify the activities that NDEQ and EPA will undertake as partners of the Facility Identification Integration Activities. As partners, each will work cooperatively to implement an exchange of facility identification data pertaining to Nebraska sites/facilities for incorporation into the Nebraska Integrated Information System(IIS) and the EPA Facility Registry System(FRS). Each partner will provide internet access to the data, making it available for use by each partner, businesses, interest groups, and the public in general.

II. BACKGROUND

The partners represent Federal and State Government whose responsibilities in general are for the protection of the environment. As part of their responsibilities, the partners collect and maintain data to support their agency's environmental program interest activities. The consistent identification of facilities within each agency and between agencies is key to the proper use of other data collected by agency environmental programs. It ensures that NDEQ and EPA recognize the same universe of regulated facilities in Nebraska and how these facilities relate to environmental program interests, and their associated data.

How the pieces fit together



NSB Management Organization

The State/EPA IMWG chartered the NSB to oversee implementation of the Exchange Network

Network Steering Board (NSB)

EPA
Kim Nelson, OEI (Co-Chair)
Ira Leighton, EPA Region 1
Tom Curran, OAR
Stan Meiburg, Region 4
EPA Director: Pat Garvey

States
Bob Zimmerman, DE (Co-Chair)
Karen Bassett, PA
Gordy Wegwart, MN
Mitch West, OR
State Director: Molly O'Neill

- Integrated Product Teams
- Node Workgroup
  - *Develop a "How To"/Best Practices guide for states wanting to implement a Node in the Network.*
  - CRM
  - Registry
  - DET
- TRG Workgroup
  - *Provide specific technical advice and assistance in the use of Extensible Markup Language (XML) related to the implementation of the Network.*

NSB Workgroups

- Node Group
  - Node 1.0 – State and EPA group who developed the guidance for establishing the Network Nodes (exchange point on the Network). This group has now sunset but was responsible for:
    - Exchange Network Node Protocol Document v1.1
    - Exchange Network Node Specification Document v1.1
    - Exchange Network Node Implementation Guide v1.0
  - Node Flow Configuration Group – State and EPA group establishing guidance for "configuring" a node with and data flow. Established the templates to be used to verify that all pertinent steps are addressed in moving data.
    - For example, will the partner be sending a "refresh" of data or a "replace and update" of only certain data types.

NSB Workgroups (continued)

- Technical Resource Group (TRG) – addresses all technical issues that are not related to building Network Nodes. Key work areas include:
  - Establishing DET/XML Guidelines
  - Developing and operating the Network Registry
  - Developing the Core Reference Model for "module and reusable" schema across multiple flows
  - Schema review process – ensure XML schema adheres to guidelines and data standards are incorporated. Works closely with the Environmental Data Standards Council

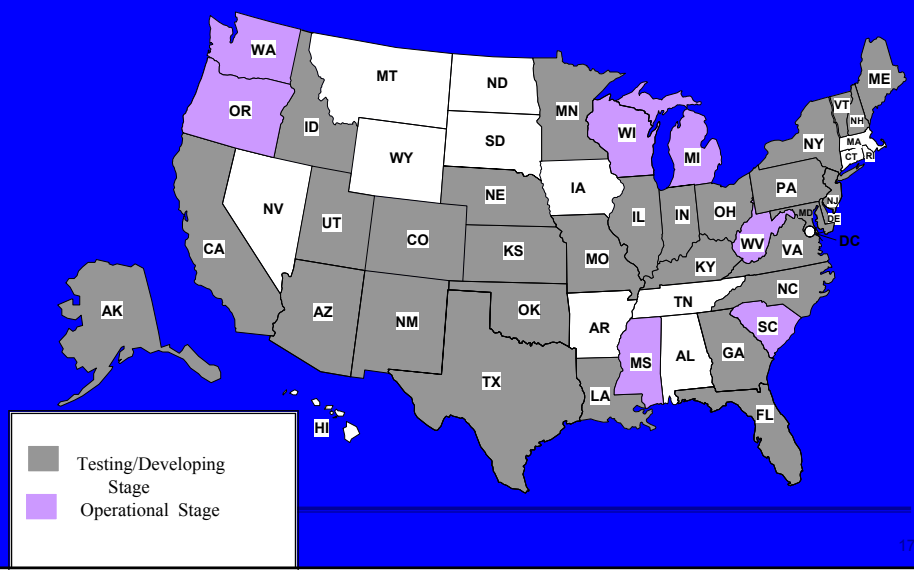
NSB Workgroups (continued)

- Core Reference Model and Schema Review process encourages “reusability” of XML tags and XML Schema
  - Reinforces data standards; and
  - Promotes data quality

Accomplishments

- **Products**
  - Node Building Specifications and Protocol Documents
  - Node Implementation Plan Guide
  - Node Security Guidelines
  - DET/XML Schema Guidelines
- **Tools**
  - Core Reference Model
  - Exchange Network Registry
  - Demonstrated Node Configurations with Executable Files
  - XML Schema available
  - XML Schema Checker Tool
- **Services**
  - Services concentrated on training, peer to peer knowledge training and maintenance of tools and help desks.
    - XML Bootcamps
    - Network Knowledge Calls
    - Knowledge Transfer Meetings
    - Operation of Exchange Network Registry
    - Operation of Network Hotline
    - Security Certificates
    - CDX Registration
    - XML Schema Review Process

Breadth of Participation - States Are Implementing the Network Design



States Are Implementing the Network Design (Cont.)

- Interest in implementing the Network continues…
  - 20% of States are leading the way
  - 60% of States are in various stages of implementation
  - 10% are in pre-planning stage
  - 10% tracking but not yet engaged

Breadth of Exchange Network

eDMR Challenge Grant
Using the EN to develop electronic Discharge Monitoring Reports with States and EPA

- Michigan, Wisconsin, Florida, Indiana, Pennsylvania, and Minnesota

Beaches Challenge Grant – Exchanging Beach Monitoring Data with EPA

- New Jersey, Delaware, New Hampshire, Georgia, California, North Carolina

Pacific Northwest Surface Water Quality Exchange Challenge Grant - Exchanging surface water monitoring data between states

- Oregon, Washington, Alaska and Idaho

Drinking Water Laboratory Challenge Grant –Exchanging drinking water laboratory results between Laboratories and states using the EN

- New Hampshire, Maine, Rhode Island, Vermont, New Jersey

Progress on Performance Measures

- Performance Goal 1 – exchanges to national EPA National Data Systems (Priority Flows)

Type	Schema Available	Goal	Progress
FRS	Yes	20	6
Beaches	Yes	7	2
NEI	Yes	12	Not due until Spring
PCS/IDEF	Yes	10	1 (eDMR only)
RCRAInfo	No	10	Not available yet
SDWIS	No	10	Not available yet

Progress on Performance Measures (cont'd)

- Performance Goal 2: Multiple flows for states
  - Target was 10-14 States doing multiple
  - Progress: None to date, but many close
- Performance Goal 3: Building Operational Nodes
  - Target: 35 States by end of 2004
  - Progress
    - 7 Operational and exchanging data
    - 9-11 Testing
    - 10 Building
    - 14 Planning

Other Progress/Trends

- While not a set performance measure – much early success has been extending the Exchange Network beyond the State to EPA exchange
  - Facility/Regulated Community to State exchanges occurring
  - State-to-State exchanges occurring
  - State agency to State agency exchanges starting
- Many states are asking for EPA out flows – from EPA to States. For example:
  - TRI data
  - NPDES data (when states aren't delegated)
  - RCRA info data

Benefits

- Advance the electronic exchange of data and information
- Reduce information collection and reporting burdens
- Facilitate the integration of data from different sources
- Enhance the security of data transmissions
- Provide timely access to environmental data
- Improve data quality

What's next?

- Harmonization of products
  - In the future, things will be easier
- Continue to look for opportunities to expedite XML schema development
- Look for opportunities to leverage the Network in non-traditional reporting relationships
- Keep up with technology changes
- Measure and demonstrate successes

Contact

www.exchangenetwork.net

Data Quality Assurance for Munitions Response Sites Investigation and Cleanup

Laura Wrench, Clem Rastatter, Versar, Inc. and Doug Maddox, USEPA

1

Purpose

- Introduce the rationale for an example QAPP for munitions investigation
- Summarize the features and content of the example QAPP for munitions investigation
- Demonstrate how the intent of the Uniform Federal Policy Quality Assurance Project Plan guidance can be implemented in non-HTW projects.

2

Example QAPP for Munitions Investigations

- **Also known as the "Example OE QAPP"**
- **Purpose:**
  - Demonstrate a manner in which the UFP-QAPP guidance may be adapted for munitions work
  - Illustrate key QA/QC steps for a munitions investigation
  - Provide fill-in-the-blank worksheets for the unique munitions components of a standard QAPP
  - Provide sufficient explanatory material so that the functions of unique QA/QC elements are clear

3

Example QAPP for Munitions Investigations

- **What it is!**
  - An example of one project team's approach to a comprehensive QAPP for a munitions investigation
  - An example of how to plan to obtain data of known quality from an investigation
- **What it is not!**
  - Model QAPP
  - New QAPP Guidance
  - A vehicle to resolve outstanding policy issues and establish national QC acceptance criteria

4

Example QAPP Scope

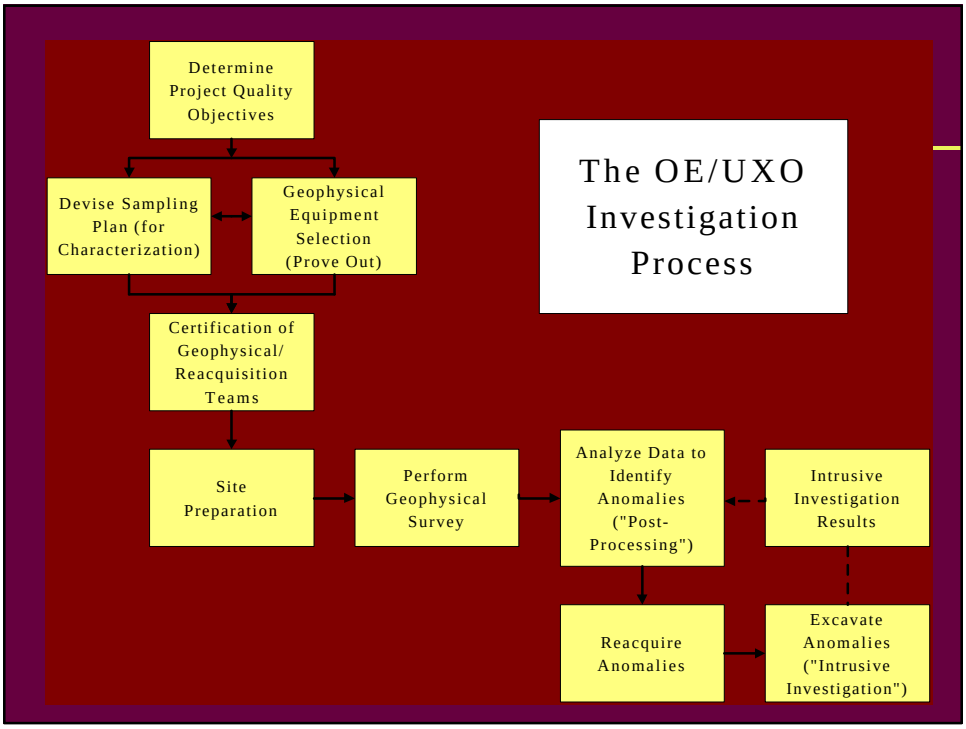
- **Initial QAPP for investigation, after completion of PA/SI**
- **Focus primarily, but not exclusively, on explosive hazards**
- **Integrate screening for presence of munitions constituents**
- **Decision objectives include:**
  - Identify locations, boundaries and depths of areas that may contain munitions
  - Determine whether and where further investigation is required for munitions constituents
  - Determine if OE scrap can be recycled or must be treated first
  - Support hazard assessment and remedy selection

5

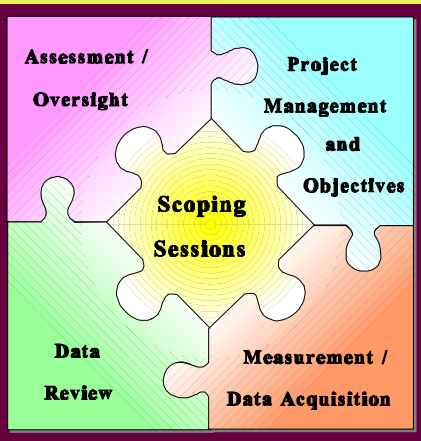
Example QAPP Scenario

- **Anonymous site (approx. 370 acres)**
- **Past activities include: weapons training, troop training, ordnance disposal**
- **Primary sources:**
  - Firing point
  - Range safety fan
  - Target areas (mortar)
  - Encampment area
  - Disposal area
- **Land use: current – general recreational; future – recreation and wildlife management**

6



Example QAPP Content



8

UFP QAPP Element 1: Project Management and Objectives

- **Project Management**
  - Project Team composition
  - Project Personnel Qualifications and Experience
  - Specialized Training
  - Project Overview and Schedule
- **Project Objectives**
  - Problem Definition
  - Project Scope (including depths of concern)
  - Project Quality Objectives (PQOs)

9

Project Objectives: Project Scope

AOC	Site ID	Area (units)	Primary Source Type	Ordnance Type(s) and Condition(s)	Depth(s) of Concern
Total Project Area (units):				Frost Depth (units):	

10

Project Objectives: PQOs

- **In the Example QAPP, Project Quality Objectives are presented in three parts:**
  - Project Decision Statements
  - Data Requirements
  - Measurement Performance Criteria

11

Example (Somewhat Quantitative) Project Decision Statement

- **Determine, to an 80% confidence level, whether or not there are target areas within the suspected target area site.**
  - If anomaly excavations provide evidence of a target area, perform confirmatory searches centered on the evidence.
  - If the confirmatory geophysical search indicates that the anomaly is part of a target area, proceed to delineate the boundaries of the area.
  - If no evidence of target areas is encountered, then the site will be deemed sufficiently investigated to conclude that there are no target areas within the site.

12

Example (More Qualitative) Project Decision Statement

- **Locate any areas in which concentrated disposal activities (i.e., open burn/open detonation or large scale burials) occurred.**
  - If the geophysical survey of this site reveals concentrated areas of anomalies, a representative sample of these anomalies will be excavated to determine if a disposal area has been located.
  - If no concentrated areas of anomalies are discovered, all identified anomalies will be excavated.
  - If a disposal area is not located, then the site will be deemed sufficiently investigated to conclude that the site does not contain a disposal area.

13

Example (More Qualitative) Project Decision Statement (cont.)

- **Upon location of any such area, determine the boundaries of the disposal area to within 10 meters.**
  - Upon completion of boundary delineation activities, the parts of the site outside of the bounded disposal areas will be deemed sufficiently investigated to conclude that they do not contain explosive hazards, as long as no evidence of other types of ordnance-related uses is discovered.

14

Example Data Requirements

Measurement Activity	Required Data
Geophysical Survey and Anomaly Identification	**Geophysical Sensor Data**
	Positional Data
Anomaly Reacquisition	**Geophysical Sensor Data**
	Positional Data
Anomaly Excavation	**Geophysical Sensor Data**
	Positional Data
	Anomaly Source Identification Data

15

Measurement Performance Criteria (MPC)

Measurement Activity:			
Site ID(s)			
Ordnance Type(s)			
Depth Range			
Data Type	Data Quality Indicator	Measurement Performance Criteria	QC Sample and/or Activity to Assess Measurement Performance

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Example MPC for Geophysical Sensor Data

- **Precision: Response above background to standard object will not vary more than +/- 20%**
- **Sensitivity: Sensor to identify 60mm mortars at a minimum of 1.5 ft bgs, and 81mm mortars at a minimum of 2 ft bgs**
- **Selectivity: Percent false positives not to exceed 15% of all identified anomalies**

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UFP QAPP Element 2: Measurement and Data Acquisition

- **Investigation Design**
  - Sampling Methods, Patterns, and Rationales
  - Geophysical Prove Out Design
  - Anomaly Identification Criteria
  - Anomaly Excavation Criteria

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Investigation Design: Sampling Method Summary

Site ID	CSM: Primary Source Type[1]	Investigation Purpose	Investigation Method	Rationale

[1]Target area, firing point, etc.

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Investigation Design: Sampling Pattern Summary

Site:					
Map Reference					
Sampling Purpose	Sampling Method	Sampling Area Boundary	Sampling Pattern	Lane or Transect Spacing (units)	Rationale

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Geophysical Prove Out Design

Description	Dimensions	Depth(s)	Number at Specified Depth	Allowed Number of Misses	Rationale

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UFP QAPP Element 2: Measurement and Data Acquisition

- **Investigation Implementation**
  - Investigation Implementation Phases and Tasks
  - Investigation Implementation Standard Operating Procedures (SOPs)
  - Geophysical and Navigational Equipment Operational Checks
  - Qualification of Geophysical Detection Process
  - Data Management Plan
  - Operational Documents and Records

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Investigation Implementation: Example Phases and Tasks

OE Investigation Phase	Tasks
Data Acquisition	**Geophysical Survey**
	Site Reconnaissance
Geophysical Anomaly Identification	**Data Processing**
	Data Analysis
Anomaly Intrusive Investigation	**Anomaly Reacquisition**
	Anomaly Excavation
	Ordnance Disposal
	Ordnance Debris Management

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Investigation Implementation: Operational SOPs

SOP Reference Number	Project Phase	Task	Responsible Organization	Title, Revision Date and/or Number	Equipment Type or Instrument	Comments

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Investigation Implementation: Equipment Checks

Equipment	Operational Checks	Frequency	Responsible Person	Acceptance Criteria	Corrective Action	SOP Reference

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Investigation Implementation: Detection Operations Qualification

Team Name/ Function Tested	Qualification Criteria	Scoring

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Investigation Implementation: Example Data Management Tasks

Geophysical Investigation Phase	Data Management Tasks
Investigation Design	**Record survey patterns and produce sampling design maps**
	Manage geophysical prove out data
Data Acquisition	**Generate and load transect navigation waypoints to DGPS receivers**
	Program field data forms onto handheld computers
Geophysical Anomaly Identification	**Manage raw and processed geophysical and navigation data**
Anomaly Intrusive Investigation	**Produce anomaly dig sheets**
	Manage anomaly excavation data
	Manage ordnance destruction data
Data Analysis and Reporting	**Provide results of GIS data base queries, maps presenting investigation results**

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Investigation Implementation: Example Documents and Records

Project Phase	Task	Record
Geophysical Data Acquisition	**Geophysical Survey**	**Field notes, Digital Geophysical data file, Navigation data file**
Geophysical Data Analysis	**Data Processing**	**Merged data file**
Geophysical Data Analysis	**Data Analysis**	**Analysis Records, "dig sheets," geophysical Maps**
Intrusive Investigation	**Anomaly Reacquisition**	**Anomaly reacquisition forms, field notes**
Intrusive Investigation	**Anomaly Excavation**	**Anomaly identification form, Ordnance ID form, field notes**
Intrusive Investigation	**Ordnance Disposal**	**Ordnance disposition database**

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UFP QAPP Element 3: Assessment and Oversight

- **Munitions Investigation QC**
  - Quality Control SOPs
  - In-process assessments (surveillance, audits)
  - Acceptance sampling
- **Quality Control Documentation**
- **Corrective Action System**

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Munitions Investigation QC: Quality Control SOPs

QC SOP Reference Number	Title, Revision Date and/or Number	Project Phase	Task	Equipment Type or Instrument	Comments

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Munitions Investigation QC: In-Process Assessments

Task	Assessment Purpose	Assessment Method	Assessment Frequency/ Minimum	Acceptance Criteria	Corrective Action	Person(s) Responsible for Ensuring Corrective Action	QC SOP	Operational SOP

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Munitions Investigation QC: Acceptance Sampling

Task/ Attribute	Sample Unit	Lot Definition	Sampling Frequency or Number/ Criteria	Acceptance Criteria	Corrective Action	Person(s) Responsible for Ensuring Corrective Action	QC SOP	Operational SOP

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Quality Control Documentation

Type of Report	Frequency (daily, weekly, monthly, quarterly, annually, etc.)	Projected Delivery Date(s)	Person(s) Responsible for Report Preparation (Title and Organizational Affiliation)	Report Recipient(s) (Title and Organizational Affiliation)

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UFP QAPP Element 4: Data Review

- **Verification**
  - Completeness check
- **Validation**
  - Compliance with contract and procedures
  - Compliance with QAPP requirements
- **Data Usability Assessment**
  - Validation of assumptions of sample design
  - Assessment of overall quality of investigation

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Data Review: Verification

Verification Input	Description	Internal/ External	Responsible for Verification (Name, Organization)

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Data Review: Validation

Validation Area	Validation Input(s)	Description	Responsible for Validation (Name, Organization)

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Data Review: Example Data Usability Assessment

Site ID:	Expected CSM Primary Source Type:	Investigation Method (circle one): Geophysical Survey Site Reconnaissance
How well did the investigation implementation for this site conform to contract and plan specifications?		
Did the investigation data for this site meet the applicable PQOs?		
Briefly describe the investigation results for this site. Summarize the results of all anomaly excavations undertaken at the site.		
Do the investigation results tend to confirm or refute the expected CSM primary source type for this site. Provide a brief explanation for this judgment.		
If the results tend to confirm the CSM, was sufficient data collected to perform a baseline hazard assessment and an analysis of alternatives for the site? If not, describe additional information required to meet these requirements.		
If the results tend to refute the CSM, what CSM primary source type is indicated by the results? Has sufficient information been collected to perform a baseline hazard assessment and an analysis of alternatives for the new CSM type? If not, describe additional information required to meet these requirements.		
Provide any additional comments regarding the usability of the data for decision making about this site:		

Example QAPP Development Plan

- Use a small team of experts to assist in identifying and developing issues for the example QAPP
- Expand the development discussion with the DoD/EPA CSM ad hoc working group – Winter 2003
- Publish example QAPP for formal review (by DoD and EPA, as well as IDQTF) – Summer 2004
- Respond to comments and complete document

38

Understanding Analytical Data Quality for Project Managers

Presented by Fred McLean, NAVSEA

Purpose

- **Assist project managers with managing analytical data quality**
- **Introduce the DoD *Quality Systems Manual for Environmental Laboratories* (QSM)**

04-004-2

DoD Quality Systems Manual

- **Provides requirements for a laboratory quality system**
- **Describes content of the lab's quality manual**
- **Topics include:**
  - Organization and Management
  - Quality System
  - Personnel
  - Measurement and Traceability and Calibration
  - Essential QC Procedures (NELAC and DoD Appendices)

04-004-3

Why Should You Care About Data Quality?

- **Because the data quality must be appropriate to the decision being made and defensible.**

04-004-4

Decision Making for Environmental Projects

- Many of the important decisions are based on analytical data
- Without the appropriate level of data quality the actions taken may not be correct:
  - **e.g., spending money for cleanup compliance when none is required.**
  - **e.g., believing permit is in compliance when there are risks of significant fines or even impacts to human health**

04-004-5

Uncertainty

- **Regardless of how samples are collected and analyzed, there is always some amount of uncertainty, or measurement error, in the data.**
- **Uncertainty does not necessarily mean the data are not usable; it indicates how good the data are in relation to data needs.**

04-004-6

Uncertainty (cont.)

- **Data uncertainty is the result of the interaction of many factors, including:**
  - **Sampling locations**
  - **Sample handling and storage**
  - **Sample preparation**
  - **Analytical methods used**
  - **Sample matrix**
  - **Sample analysis**
  - **Data interpretation**

04-004-7

Systematic Planning Process (SPP)

- **SPP is a graded, common-sense approach to planning that requires the project team to:**
  - **Develop decision statements**
  - **Develop project quality objectives (PQOs)**
  - **Establish how to assess whether the PQOs have been met**

04-004-8

PQOs and Measurement Performance Criteria (MPC)

- **PQOs are statements that clarify the objectives of the project and define data needs**
- **MPC are acceptance limits to determine if PQOs have been met; associated with data quality indicators:**
  - **Precision**
  - **Accuracy**
  - **Comparability**
  - **Completeness**
  - **Representativeness**
  - **Sensitivity**

04-004-9

Sensitivity

- **Sensitivity criteria are usually reflected in:**
  - **Detection limit**
  - **Quantitation limit**
  - **Reporting limit**
  - **Action limit**

04-004-10

Sensitivity (cont.)

- **"Ideally" the relationship should be:**

  DL < QL < RL £ 100,000 x Action Limit

- **This is not always possible**
  - **Work with the laboratory to optimize methods**
  - **Work with the regulators to adjust action limits**

04-004-11

Accuracy

- **Can be measured by a laboratory control Sample (LCS)**
  - **QC sample prepared in a clean matrix and carried through the preparation and analytical process**
- **QSM Appendix DoD-D lists control limits based on a multi-laboratory LCS study**

04-004-12

Target Analytes

- **Long analyte lists may increase uncertainty; make it harder to optimize the method.**
- **Use the information about the site and the activities that occurred on it to narrow the list of actual target analytes.**
- **QSM Appendix DoD-C is a starting place.**

04-004-13

Method Selection

- **Select sample preparation and analytical methods to achieve the desired limits**
- **Driven by**
  - **Target analytes**
  - **Sample matrix**
  - **Sensitivity, accuracy, etc.**
- **Work with lab or a project chemist during the planning phase**
  - **Potentially optimize the methods for the target analytes**

04-004-14

Laboratory Selection

- **Laboratory must have a quality system in place and be able to meet specific analytical data requirements.**
  - **Do not assume this is true for all laboratories.**
- **A laboratory with a good quality system in place must still be evaluated for project-specific needs.**

04-004-15

Laboratory Selection (cont.)

- **Important factors to consider include:**
  - **Sample matrix**
  - **Target analytes**
  - **Sample preparation methods**
  - **Analytical methods / sensitivity**
  - **Laboratory's capacity**
  - **Data turnaround time**

04-004-16

Laboratory Selection (cont.)

- **Other factors to consider include:**
  - **NELAP-accreditation**
  - **Recent DoD assessment(s)**
  - **Participation in proficiency testing (PT) programs**

04-004-17

What the Future Holds

- **Development of Version 3 of DoD Quality Systems Manual**
  - **Reorganized to fit ISO 17025 and NELAC**
- **Adoption of *performance*-based approaches vs. prescribed methods**
- **Straight forward definitions for detection, quantitation, and reporting limits**
- **Two-day training for project managers on the QSM**

04-004-18

Conclusion

- **Data generation and evaluation is still a flawed process.**
- **The DoD QSM and other DoD efforts are helping laboratories and project managers to improve the data they collect and correctly use the data they have.**

04-004-19

Conclusion

- **Questions ??**

04-004-20

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04-004-21